New Mexico Board of Pharmacy
CATEGORY 2 & 3 STERILE COMPOUNDING INSPECTION REPORT

Facility Name	License #
Street Address	City
Zip Code	Phone #
Designated Person (aka PIC or Consultant RPh)	Designated Person License #
Date of Inspection:	Inspector Signature:
Official Signature:	30 Day Response

Dosage Forms of Sterile Compounding (circle all that apply)
Injections, including infusions
Ophthalmic
Aqueous preparations for pulmonary inhalation.
Baths and Soaks for live organs and tissues
Implants
Irrigations for Wounds or Body Cavities

Preparation Level (circle all that apply)	
Does the pharmacy **dispense** patient-specific CSPs pursuant to a prescription?	Yes/No
Does the pharmacy **distribute** CSPs without a prescription or compound sterile preparations for office use?	Yes/No
Does the pharmacy dispense any CSPs out of New Mexico?	Yes/No
If so, to which states are CSPs being shipped?	

If CSPs are shipped out of state, does the pharmacy have policies and procedures for proper shipping?	Yes/No
What volume of CSPs are shipped out of state? (If more than 5% of total prescriptions dispensed, the pharmacy must register as an outsourcing facility)	%
Does the pharmacy compound regularly or in inordinate amounts any CSPs that are essentially copies of commercially available drug products?	Yes/No

Category of Compounded Sterile Preparations (CSPs) made by facility. (Circle all that apply)	Category 2	Category 3

INSPECTION CHECKLIST

Inspection items with * indicate the item is a USP and/or CriticalPoint recommendation and may be considered best practice.

I. STANDARDS FOR STERILE COMPOUNDING CLEANROOM SUITE	Compliant? Yes/No/NA	COMMENTS
Buffer Room shall maintain a well-lighted work environment with an average of 80-150 foot candles		
Ceilings, walls, floors, doors, door frames, fixtures, shelving, counters, cabinets in buffer area must be smooth, impervious, free from cracks and crevices and non-shedding so they can be cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.		
Floors in the cleanroom suite must include coving to the sidewall, or the juncture between the floor and the wall must be caulked. Floors must be smooth, impervious and free of cracks and crevices and non-shedding. 1. Tacky Mats are not allowed in ISO Class Spaces 2. *Avoid fatigue mats, especially those that feature at waffle bottom		
Walls in the cleanroom suite must be fixed and constructed of, or may be covered with, durable material (e.g., epoxy painted walls or heavy-gauge polymer). Panels must be joined together and sealed to each other and the support structure.		

If ceilings consist of inlaid panels, the panels must be caulked around each panel to seal them to the support frame.		
Junctures between the ceiling and the walls must be sealed to eliminate cracks and crevices where dirt can accumulate.		
Dust-collecting overhangs, such as utility pipes, and ledges, such as windowsills should be minimized in the cleanroom suite. If overhangs or ledges are present, they must be easily cleanable.		
The exterior lens surface of ceiling light fixtures must be smooth, mounted flush, and sealed.		
No sources of water or floor drains in buffer area		
Work surfaces shall be constructed of smooth, impervious materials such as stainless steel or molded plastic, easily cleaned and disinfected		
Storage shelving, counters and cabinets shall be smooth, impervious materials free of cracks or crevices, non-shedding, easily cleaned and disinfected		
HEPA filtered air flow into ante and buffer areas shall be introduced at the ceiling. Air returns must be mounted low on the wall, unless a visual smoke study demonstrates an absence of stagnant airflow.		
Ante-Room has a line of demarcation between the dirty side and the clean side.		
Sink with running warm water is placed either inside or outside of the anteroom. If the sink is located outside the anteroom, it must be located in a clean space. *Sink should enable hands-free use. Sink should be deep enough to wash up to elbows.		

*The doors into the anteroom from the general pharmacy area and from the anteroom into the clean room are prevented from both being open at the same time. *By interlocking, training of personnel, or signage*. (Gaps are fine at the bottom of either door but not the top of doors). Access doors should be hands-free		
Carts used to transport components or equipment into classified areas must be constructed from nonporous materials with cleanable casters and wheels to promote mobility and ensure ease of cleaning and disinfection.		
Carts must not be moved from the dirty side to the clean side of the anteroom unless the entire cart, including casters, is cleaned and disinfected.		
* Pass-throughs are best placed between the buffer room and the non-classified space to reduce the traffic and introduction of particles/microbes into the anteroom. If a <u>pass-through</u> is located in the anteroom it should be on dirty side.		
Pass-throughs are enclosed chambers with sealed doors on both sides. Doors <u>should</u> be interlocking.		
No shipping carton(s) or other corrugated or uncoated cardboard are allowed in the cleanroom suite. Removal of immediate packaging designed to retain sterility or stability is allowed in PEC.		
Only authorized personnel required for compounding and cleaning shall be permitted in the buffer area.		

Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the cleanroom suite, and they should be low-shedding and easily cleaned and disinfected. Avoid excessive amounts of supplies.		
*Trash receptacle at least 6 feet away from PEC – Best Practice		
Temperatures and humidity are monitored in each room of cleanroom suite each day compounding is performed. Should be ≤ 68°F and relative humidity of ≤ 60%. Device accuracy must be verified annually or as required by manufacturer		
Components (ingredients used in compounding) are handled and stored in a manner that prevents contamination, mix-ups, and deterioration and under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers.		
Temperature in CSP & component storage areas are monitored at least once daily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable.		
Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer.		

II. CERTIFICATION & DOCUMENTATION	Compliant? Yes/No/NA	COMMENTS
All Primary Engineering Controls are re-certified by an independent qualified contractor and maintain ISO Class 5 or better air quality during dynamic conditions. PECs must be recertified every 6 months and whenever the device is relocated or the physical structure of the buffer area or ante-area has been altered.		

Buffer room independently certified to maintain ISO Class 7 conditions under dynamic conditions every 6 months. (Request Documentation)		
Ante-room independently certified to maintain ISO Class 8 conditions (or ISO Class 7 if it serves Hazardous Drug compounding buffer room) under dynamic conditions every 6 months. (Request Documentation)		
Dynamic airflow smoke pattern testing must be performed initially and every 6 months in primary engineering controls under dynamic conditions to confirm unidirectional airflow. The airflow smoke patterns should be documented, ideally with video.		
If air returns in the cleanroom suite are not low on the wall a visual smoke study has been performed to demonstrate an absence of stagnant airflow. Does not need to be under dynamic operating conditions. Only performed one time but must be repeated if equipment is placed in a different location. This smoke study should be documented, ideally with video.		
HEPA filter leak tests performed in primary engineering controls every 6 months.		
HEPA filter leak tests performed in secondary engineering controls every six months.		
Viable volumetric air sampling shall occur throughout all ISO areas using an impaction air sampler at least every 6 months for Category 2 and at least monthly for Category 3. Sampling must occur during dynamic conditions. At least 1000 liters of air must be tested. Sampling locations shall be defined in SOPs in a diagram or map. Ask for Documentation.		

<table>
<tr><td>Surface sampling shall be performed in all ISO classified areas and pass-through chambers connecting to classified areas, <u>at least monthly</u> for Category 2.

For facilities that compound Category 3 CSPs, surface sampling must be done prior to assigning a BUD longer than the BUD limits for Category 2 CSPs and <u>at least weekly</u>.

Sampling locations shall be defined in SOPs in a diagram or map.</td><td></td><td></td></tr>
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<tr><td rowspan="3">Viable air and surface samples did not exceed recommended USP action levels (or internal action levels if more restrictive).

<u>Classification</u> <u>Air Sample</u> <u>Surface Sample</u>

ISO Class 5 >1 CFU/m3 >3 CFU/plate
ISO Class 7 >10 CFU/m3 >5 CFU/plate
ISO Class 8 >100 CFU/m3 >50 CFU/plate

CFUs are TOTAL of bacterial plus fungal/mold plates.</td><td>PEC Air</td><td>PEC Surface</td></tr>
<tr><td>Buffer-Room Air</td><td>Buffer-Room Surface</td></tr>
<tr><td>Ante-Room Air</td><td>Ante-Room Surface</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td>An attempt is made to identify any microorganism recovered to the genus level when CFUs detected by air or surface sampling exceeded action levels.</td><td></td><td></td></tr>
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If CFU action levels for a specified air and surface sampling are exceeded, a corrective action plan must be documented. The corrective action plan must be dependent on the cfu count and the microorganism recovered. The extent of the investigation should be consistent with the deviation and should include an evaluation of trends. Some examples of corrective action include process or facility improvements, personnel training, cleaning and disinfecting, or HEPA filter repair and/or replacement. Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective. The corrective action plan must be documented and should include resampling of failed areas to confirm corrective action was successful.		
All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective.		
Regular review of sampling data is performed to detect trends and review of trending data is documented.		
Buffer room must have a minimum of 30 air changes per hour (ACPH) of HEPA filtered air. At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling.		
Anteroom must have a minimum of 20 ACPH		
A pressure differential monitoring device is used to continuously monitor pressure differentials. Quantitative pressure results must be reviewed and documented at least daily on the days when compounding occurs.		

Pressure shall be at least 0.02-inch water column between buffer and ante room & at least 0.02-inch water column between ante room and unclassified areas.	Ante – Pharm Differential	
	Buffer – Ante Differential	
If turned off, the PEC shall be disinfected and allowed to operate for a minimum of 30 minutes before any sterile compounding takes place. If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off except for maintenance		
Has the PEC been moved since last inspection (aside from routine cleaning)? If so, was it recertified?		
PECs are located within an ISO Class 7 buffer room?		
Integrated Vertical Laminar Flow Zones are separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface.		
Incubators must not be put in the buffer or ante-room as they are a biohazard.		
Media devices (plates, etc..) must be incubated at 30°–35° for no less than 48 h and then examined for growth. Followed by incubation of the media device at 20°–25° for no less than 5 additional days and examined for growth again. To shorten the overall incubation period, two surface sampling media devices may be collected for each sample location and incubated concurrently. Media must contain neutralizing additives (e.g., lecithin and polysorbate 80) to neutralize the effects of residual disinfecting agents.		

Automated Compounding Devices: Must keep a daily record of accuracy assessment and perform a weekly review of the results. Ask for Documentation.		
Automated Compounding Devices: observed every 30 days by the operator during the mixing process to ensure the device is working properly. Ask for Documentation.		
Automated Compounding Devices: have data entry verified by a pharmacist prior to compounding or have accurate final documentation of compounded preparations to allow for verification of ingredients by a pharmacist prior to dispensing.		
Automated Compounding Devices: have accuracy of delivery of the end product verified according to written policies and procedures. Ask for Documentation.		
Supplies (e.g., beakers, utensils, needles, syringes, filters, and tubing sets) in direct contact with CSPs are sterile and depyrogenated.		
Library of current references (hard copy or electronic) shall be available including: USP/NF or USP on Compounding: A Guide for the Compounding Practitioner or USP Compounding Compendium; New Mexico pharmacy rules and regs; specialty references as appropriate.		
Sterile Preparations in a Home Setting: Documentation of patient training is available.		

Sterile Preparations in a Home Setting: Facility provides a 24-hour toll free telephone number for use by patients of the pharmacy		
Sterile Preparations in a Home Setting: There is documentation of an ongoing quality assurance program that monitors patient care and pharmaceutical care outcomes.		

III.FUNCTIONING WITHIN COMPOUNDING AREA	Compliant? Yes/No/NA	COMMENTS
Only pharmacists, pharmacist interns and pharmacy technicians are performing sterile compounding.		
All items shall be wiped (not just sprayed) using low-lint wipers with sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA by personnel wearing gloves prior to introduction into the clean side of anteroom(s) or placed into pass-through chamber(s).		
Just before any item is introduced into the PEC, it must be wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. (Sterile supplies in sealed pouches may be removed from the pouches as the supplies are introduced into the PEC without the need to disinfect the individual sterile supply.)		
Critical sites (e.g., vial stoppers, ampule necks, and intravenous bag septums) must be wiped with sterile 70% IPA in the PEC. Sterile 70% IPA must dry before entry.		
Critical sites should always have benefit of HEPA filtered First Air. Nothing may block first air from the HEPA filter (including compounder and supplies) and an exposed critical site while compounding.		

Application of sterile 70% IPA to gloves must occur immediately before compounding and regularly throughout the compounding process.		
When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air is documented and internal procedures are developed to ensure that adequate recovery time is allowed after opening and closing the RABS.		
Labeling: Appropriate Patient Specific Labels are given to CSPs. See 16.19.36.15A. (5) NMAC & USP 797 • Assigned internal identification number (e.g., barcode, prescription, order, or lot number) • Patient name; • Solution, ingredient names, amounts; • Beyond use date, and time when applicable; • Route of administration; • Dosage Form; • Directions for use, including infusion rates, specific times scheduled, when appropriate and applicable; • Storage conditions if other than controlled room temperature • Identifier of person preparing the product and, if prepared by supportive personnel (i.e., pharmacist intern or pharmacy technician), the identifier of the pharmacist that completed the final check; • A statement whether it is a single-dose or multiple-dose container • When appropriate, ancillary instructions such as storage instructions or cautionary systems, including hazardous material warning labels and containment bags; and • Device instructions when needed; • If dispensed for other than inpatient use, the label shall include all other required information. • The labeling on the CSP should indicate that the preparation is compounded.		
Batch Labels are given to each CSP in a batch. See 16.19.36.15A. (4) NMAC		
A Compounding Record is created for each CSP and includes the following: • Name, strength or activity, and dosage form of the CSP • Date and time of preparation of the CSP		

• Assigned internal identification number • A method to identify the individuals involved in the compounding process and verifying pharmacist • Name, weight or volume, and strength or activity of each component • Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredients • Total quantity compounded and final yield • Assigned BUD and storage requirements • Results of QC procedures (visual inspection, filter integrity testing, etc..) • MFR reference if applicable • Calculations made to determine and verify quantities and/or concentrations of components if applicable. • Date, run and load number if autoclave or dry heat oven terminal sterilization is performed.		
A Master Formulation Record is created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared in a batch. See USP797 & 16.19.36.15 B.(1)		
Sterile Compounding SOPs are reviewed at least every 12 months by the designated person(s). The review must be documented.		
Repackaging of sterile products or preparations from its original container into another container are prepared according to all applicable USP 797 requirements.		
Compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), are clearly separated from other compounding activities and equipment used in CSP preparation activities and controlled by specific SOPs to avoid cross-contamination.		

IV. SINGLE AND MULTI-DOSE CONTAINERS	Compliant? Yes/No/NA	COMMENTS
Closed, sealed, multidose containers have a BUD of 28 days once entered, unless otherwise specified by manufacturer.		

Single-dose containers have a BUD of 12 hours if entered and remain in an ISO 5 environment and labeled storage requirements are maintained.		
Ampules are always single use and may never be saved or stored.		
Pharmacy bulk packages are only entered or punctured in an ISO Class 5 PEC and used according to the manufacturer's labeling.		

V. CLEANING OF COMPOUNDING AREAS	Compliant? Yes/No/NA	COMMENTS
The PEC and equipment inside the PEC is cleaned and disinfected daily on days when compounding occurs. This may be accomplished in one step with an EPA-registered one-step disinfectant cleaner. Cleaning, disinfecting and sporicidal agents used within the PEC **must** be sterile.		
Surfaces within the PEC are disinfected with sterile 70% IPA after cleaning, disinfecting or application of a sporicidal disinfectant. Sterile 70% IPA must also be applied immediately before initiating compounding, every 30 mins during continuous compounding, and when surface contamination is known or suspected.		
All cleaning materials are low-lint. Cleaning materials (sponges, wipers, mop heads) should be disposable.		
Cleaning tools are dedicated and only for use in classified area. Reusable cleaning tools must be made of cleanable materials (e.g., handles should not be made of wood or any other porous material) and must be cleaned and disinfected before and after each use.		

Personnel that clean buffer and ante-areas are properly trained and gown and glove properly for all cleaning procedures (garbing order and guidelines same as for compounding).		
Floors in buffer area and ante–area are cleaned and disinfected daily on days when compounding occurs. Ask for Log.		
Work surfaces outside the PEC and pass-through chambers are cleaned and disinfected daily on days when compounding occurs. Ask for Log.		
Surfaces of the sink(s) must be cleaned and disinfected each day of use, and a sporicidal disinfectant must be applied at least monthly.		
Walls, doors, ceilings, storage shelving and bins and equipment outside the PEC are cleaned and disinfected monthly. (This cleaning may be broken up into multiple days as long as done approximately the same time every month) Ask for Log.		
APPLICATION OF SPORICIDALS		
A sporicidal disinfectant must be applied monthly to all PECs, and all areas (floors, walls, ceilings, shelving, pass-throughs, etc…) and equipment within the cleanroom suite (SECs) for facilities compounding Category 2 CSPS. Ask for Log.		
For facilities compounding Category 3 CSPs a sporicidal disinfectant must be applied weekly in the following areas: PEC and equipment inside the PEC, pass-through chambers, work surfaces outside the PEC, and floors. All other areas in the facility compounding Category 3 CSPs require a monthly sporicidal application.		

VI. PERSONNEL TRAINING & TESTING	Compliant? Yes/No/NA	COMMENTS
All personnel who compound sterile preparations (pharmacists, technicians, interns and supervising pharmacists) have completed site-specific didactic and experiential training with competency evaluation through demonstration and testing prior to compounding sterile preparations (this is non-transferable). Ask for Documentation. Refer to current training requirements in 16.19.36.13 NMAC.		
Technicians have completed 100 hours of experiential training in sterile compounding prior to compounding (This training is transferable)		
Compounding personnel shall complete training and demonstrate competency prior to compounding and every 12 months in at least the following Core Skills: • Hand hygiene • Garbing • Cleaning and disinfection • Calculations, measuring, and mixing • Aseptic technique • Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components) • Use of equipment • Documentation of the compounding process (e.g., master formulation and compounding records) • Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area • Proper use of PECs • Principles of movement of materials and personnel within the compounding area		
Prior to compounding, personnel have passed an initial garbing competency evaluation with gloved fingertip testing three times in a row. Action required if the tests yield any garbing deficiencies, or if the sampling results are > 0 colony-forming units (CFU)/plate on the three initial validations. Ask for Documentation.		

Personnel compounding Category 2 CSPs must successfully complete a garbing competency evaluation with gloved fingertip testing at least one time every 6 months. Personnel compounding Category 3 CSPs must pass a garbing competency evaluation with gloved fingertip testing at least one time every 3 months.		
Prior to compounding, personnel have passed an initial aseptic manipulation competency evaluation. The aseptic manipulation competency evaluation consists of a visual observation, media-fill testing, followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area. When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person Successful completion of the gloved fingertip and thumb sampling after media-fill testing is defined as ≤3 cfu as a total from both hands.		
Personnel compounding Category 2 CSPs must successfully complete an aseptic manipulation competency at least one time every 6 months. Personnel compounding Category 3 CSPs must pass an aseptic manipulation competency at least one time every 3 months.		
Personnel who have direct oversight of compounding personnel must complete training and demonstrate competency initially and at least every 12 months in appropriate sterile compounding principles and practices. Personnel with direct oversight must complete a garbing competency evaluation and aseptic manipulation competency initially and every 12 months.		

VII. PERSONNEL CLEANSING AND GARBING	Compliant? Yes/No/NA	COMMENTS
Before entering buffer area, staff shall remove outer jackets, sweaters, bandanas, coats, hats, piercings, cosmetics, earbuds/headphones, and jewelry.		
Artificial nails, extenders and polish are not allowed in the cleanroom suite. Nails must be short and clean.		
Food (including gum and mints) and drinks are not allowed in the cleanroom suite.		
The order of garbing is stated in the facility's SOPs. (The order of hand washing and garbing depends on the placement of the sink.)		
Garb must be donned and doffed in an order that reduces the risk of contamination. *All garb <u>should</u> be donned in a classified area before entering the buffer room. Donning and doffing garb <u>should</u> not occur in the same area at the same time.		
<u>Handwashing Procedures:</u> • Clean underneath fingernails under warm running water using a disposable nail cleaner. • Wash hands and forearms up to the elbows with soap and water for at least 30 s. • Dry hands and forearms up to the elbows completely with <u>low-lint disposable towels or wipers</u>. • If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.		
<u>Category 2 Garbing Requirements:</u> • Low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gown or coverall). • Low-lint covers for shoes. • Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair.		

• Low-lint face mask. • Sterile powder-free gloves. • If using a RABS (i.e., a CAI or CACI), disposable gloves should be worn inside the gloves attached to the RABS sleeves. Sterile gloves must be worn over the gloves attached to the RABS sleeve.		
<u>Category 3 Garbing Additional Requirements:</u> These additional garbing procedures must be followed in the buffer room by all personnel regardless of whether Category 3 CSPs are compounded on a given day. • Exposed skin is not allowed in the buffer room (i.e., face and neck must be covered). • All low-lint outer garb must be sterile, including the use of sterile sleeves over gauntlet sleeves when a RABS is used. • The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.		
Alcohol-based hand rub is used prior to donning sterile gloves. Sterile gloves must be donned in a classified room.		
When personnel exit the compounding area, garb, except for gowns, cannot be reused and must be discarded or laundered before reuse. Gowns may be reused within the same shift by the same person, if maintained in or adjacent to the cleanroom suite in a manner that prevents contamination. For **Category 3 CSPs** disposable garb cannot be reused and laundered garb cannot be reused unless re-laundered and re-sterilized		
RABS sleeves and gloves should be changed per the manufacturer's recommendations and as defined in the facility's SOPs.		
Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA.		

VIII. ASEPTIC PROCESSING, TERMINAL STERILIZATION, AND MISC.	Compliant? Yes/No/NA	COMMENTS
Does the facility prepare Category 2 or Category 3 CSPs from nonsterile starting components?	Circle Answer: Yes or No (if No, skip to letter **A**)	
Pre-sterilization procedures (weighing, mixing) must be performed in no less than ISO 8 environment (ante-room or buffer room).		
Pre-sterilization procedures must be performed in single-use containment glove bags, containment ventilated enclosures (CVEs), BSCs, or CACIs to minimize the risk of airborne contamination.		
CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every 6 months.		
PECs used for sterile and nonsterile compounding (e.g., pre-sterilization procedures) are placed in separate rooms unless the buffer room can maintain an ISO Class 7 classification during particulate generating activities. Co-located PECs are at least 1 meter apart and particle-generating activities are not performed during sterile compounding processes.		
Personnel are garbed and gloved during pre-sterilization procedures the same as when performing compounding.		
Must have certificates of analysis (COAs) available for APIs used in the production of CSPs. The accuracy of identities, concentrations, amounts and purities of ingredients are specified on COAs.		

APIs from the United States must be manufactured by an FDA-registered facility. APIs from outside the United States must comply with laws and regs of the applicable regulatory jurisdiction.		
Non-API components must be accompanied by documentation (e.g., COA, labeling) that includes the specifications and test results and shows that the component meets the specifications		
Non-API components from the US should be manufactured by an FDA-registered facility (must be from and acceptable and reliable source).		
Non-API components from outside the US must comply with laws and regs of the applicable regulatory jurisdiction.		
APIs and components used for compounding are not labeled “not for pharmaceutical use”, “not for injectable use”, “not for human use” or an equivalent statement.		
APIs and components used for compounding are not expired. *If the COA does not have an expiration date – the expiration becomes 1 year from the date that the pharmacy received the component (container should be labeled with the date received).		
All components are reinspected before use to ensure correct identity, appropriate quality, within expiry date, have been stored under appropriate conditions.		
Sterilization method(s) used do not degrade CSP physical and chemical stability (e.g., affecting its strength, purity, or quality) or packaging integrity.		
*Terminal Sterilization Devices (Dry-heat ovens and autoclaves) are recommended to be placed in an ISO-Class Room.		

Injectable CSPs that contain nonsterile components or that come into contact with nonsterile devices during compounding are sterilized within 6 hours after compounding to minimize bacterial endotoxins.		
A. Are the Category 2 or Category 3 CSPs aseptically processed (either compounded with only sterile starting ingredient(s) or compounded with nonsterile ingredient(s) followed by sterilization by filtration), or terminally sterilized (e.g., steam, dry heat, or irradiation)? {Note: If one or more starting components being used to compound is not sterile, sterility must be achieved through sterilizing filtration or terminal sterilization}	Circle Answer: Aseptically Processed (If sterilized by filtration go to **B**. below; if only sterile starting ingredients are used go to **E.** below) Terminally Sterilized (Skip to **C** and/or **D** below)	
B. Filtration (aseptically processed)		
If Category 2 or 3 CSPs are sterilized by filtration the filters are sterile, pyrogen free, have a nominal porosity of 0.22 µm or smaller and are appropriate for pharmaceutical use.		
Sterilization by filtration occurs entirely within an ISO Class 5 environment.		
Filters used for sterilization have sufficient capacity for required volume and to filter without replacement.		
Each filter that is used shall undergo integrity test such as bubble-point test. All bubble-point test results are kept. Filters cannot be reused. Bubble-point testing is done after filtration not before. (Bubble-point testing is done in-house by pharmacist or technician.)		
C. Terminal Sterilization by Steam Heat		

The terminal sterilization process is intended to achieve a probability of a nonsterile unit (PNSU) of 10−6.		
The steam supplied in the autoclave is generated using water per the manufacturer's recommendation.		
Sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of the CSP to reach and remain at the sterilizing temperature during the duration of the sterilization period. Items are placed in the autoclave to allow steam to reach CSPs without entrapment of air.		
Before filling containers to be steam sterilized, solutions are passed through a filter no larger than 1.2 µm to remove particulates.		
The effectiveness of steam sterilization must be verified and documented with each sterilization by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus and other confirmation methods such as physicochemical indicators.		
A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure).		
D. Terminal Sterilization by Dry Heat		
The terminal sterilization process is intended to achieve a probability of a nonsterile unit (PNSU) of 10−6.		
Dry heat sterilization shall only be used when steam sterilization cannot be used due to damage caused by moisture to the preparation or ineffectiveness.		
Before filling containers to be dry heat sterilized, solutions are passed through a filter no larger than 1.2 µm to remove particulates.		

The calibrated oven is equipped with temperature controls and a timer. A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (e.g., deviations in temperature or exposure time).		
The effectiveness of the dry heat sterilization method must be verified and documented with each sterilization run or load using appropriate biological indicators such as spores of Bacillus atrophaeus and other confirmation methods (e.g., temperature-sensing devices).		
E. Sterility, Endotoxin, Stability and Miscellaneous Testing		
Category 2 or 3 CSPs have had sterility testing performed?	Circle Answer: Yes or No (Note: Sterility testing is only required for Category 2 CSPs that are assigned a BUD that requires sterility testing. Sterility testing is required for all Category 3 CSPs)	
If sterility testing is performed, the minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units.)		
Sterility testing is according to USP <71> or a validated alternative and noninferior method. Membrane filtration is used if appropriate and filters are rinsed according to USP <71>. Direct inoculation is done only when membrane filtration cannot be carried out. Volume inoculated does not exceed 10% of the culture media volume. Growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP <71>. TSB or SCD is incubated at 20-25C for 14 days; FTM is incubated at 30-35C for 14 days.		

A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method.		
Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented.		
Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing and Category 3 injectable CSPs compounded from one or more nonsterile component(s) must be tested to ensure that they do not contain excessive bacterial endotoxins.		
Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that does not require sterility testing should be tested for bacterial endotoxins.		
In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species.		
The BUD assigned to a Category 3 CSP must be supported by stability data obtained using a stability-indicating analytical method that is able to distinguish the active ingredient from its degradants and impurities and quantify the amount of the active ingredient.		
Category 3 CSPs are prepared according to the exact formulation (API and other ingredients of identical grade and procedures) from which the stability data are derived.		

Category 3 CSPs are packaged and stored in a container closure of the same materials of composition as that used in the study.		
The compounding facility must have documentation of the stability study, including a description of the methodology, validation of the method, the stability-indicating analytical method, and all of the results of the study.		
Category 3 CSPs that are injections or an ophthalmic solution have particulate-matter testing conducted once per formulation with acceptable results. (See Particulate Matter in Injections <788> or if it is an ophthalmic solution, Particulate Matter in Ophthalmic Solutions <789>)		
For Category 3 CSPs, the container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD – performed once for each formulation and for each container closure system in which it will be packaged. See <1207>		
Surface sampling is conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used.		
Dry heat depyrogenation is used to render glassware, metal, and other thermostable containers and components pyrogen free. The exposure period includes sufficient time for items to reach the depyrogenation temperature; items remain at the depyrogenation temperature for the duration of the depyrogenation period.		
Non-thermostable items are depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., Sterile Water for Injection or Sterile Water for Irrigation) and then thoroughly drained or dried immediately before use in compounding.		

The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using ECVs to demonstrate the cycle achieves a greater than or equal to 3-log endotoxin reduction. The effectiveness of the depyrogenation cycle is re-established if there are changes to the depyrogenation cycle. Cycle verifications are documented.		
F. Multiple-dose CSPs		
Does the facility compound multiple-dose CSPs? If so, they must be prepared as a Category 2 or Category 3 CSP.		
Do aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with Antimicrobial Effectiveness Testing <51>. Facility may rely on testing either conducted once for each formulation in the particular container closure system (CCS) in which it will be packaged or results from an FDA-registered facility or published in peer-reviewed literature (provided the formulation and CCS is exactly the same).		
After a multiple-dose CSP container is initially entered or punctured, the multiple-dose container must not be used for longer than the assigned BUD or 28 days if supported by antimicrobial effectiveness testing, whichever is shorter. (Multiple-dose, aqueous, nonpreserved CSPs intended for topical, including topical ophthalmic, administration may be given a 28-day BUD, but only if: prepared as Category 2 or 3, prepared for a single patient, and labeled to be discarded within 24 hours (CRT) or 72 hours (refrigerated) once opened.		
The container closure system used to package the multiple-dose CSP must be evaluated for and conform to container closure integrity		
G. Component CSPs		
Does the facility compound CSPs to be used as components to prepare final CSPs?		

Component CSPs are assigned BUDs consistent with USP 797?		
Multiple-dose components meet the criteria for antimicrobial effectiveness testing. After entering a multi-dose CSP they are not used for longer than 28 days or the BUD whichever is shorter.		
When a compounded single-dose CSP or CSP stock solution is used as a component to compound additional CSPs, the original compounded single-dose CSP or CSP stock solution must be entered or punctured in ISO Class 5 environment and stored under the conditions upon which its BUD was based.		
A single-dose component CSP may be used for sterile compounding for up to 12 h or its assigned BUD, whichever is shorter, and any remainder must be discarded.		
The final CSP made using component CSPs is assigned a BUD consistent with USP 797. CSPs prepared from one or more compounded components should generally not have a BUD exceeding the shortest BUD of any of the individual compounded components.		

IX. IMMEDIATE-USE CSPS	Compliant? Yes/No/NA	COMMENTS
Does the facility compound immediate-use CSPs?		
When all the following conditions are met, compounding of CSPs for direct and immediate administration is not subject to the requirements for Category 1, Category 2, or Category 3 CSPs:		
Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction		

of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.		
Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.		
The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies).		
The preparation involves not more than 3 different sterile products.		
Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.		
Administration begins within 4 h following the start of preparation. If administration has not begun within 4 h following the start of preparation, it must be promptly, appropriately, and safely discarded.		
Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 4-h time period within which administration must begin.		

X. LYOPHILIZATION	Compliant? Yes/No/NA	COMMENTS
Sterile preparations prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport to the lyophilizer.		
A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times.		
The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product.		
The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection.		
Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy.		
Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection.		
Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations.		

The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection.		
SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications.		
The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test.		
Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation.		
Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin.		
Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record.		
In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product.		

A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record.		
Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line.		
Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free.		
Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record.		
Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record.		
Potency, radiochemical purity, or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight-based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available.		

XI. PRODUCT RELEASE/QUALITY CONTROL/QUALITY ASSURANCE	Compliant? Yes/No/NA	COMMENTS
Prior to release/dispensing every CSP undergoes a final check and visual inspection by a pharmacist including: physical appearance (color, particulates, etc..); CSP labeling compared to Rx or order; and container closure integrity. Documentation of visual inspection is in the compounding record.		
When CSPs are not released or dispensed on the day of preparation, a visual inspection is conducted immediately before its release to ensure the CSP is free from any defects such as precipitation, cloudiness, or leakage, which could develop during storage.		
CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock.		
Out-of-specifications results and defects indicating sterility or stability problems are investigated to determine the root cause and a corrective action plan is implemented and documented per facility SOPs.		
CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption and prevent inadvertent exposure to transport personnel.		
Modes of transport are selected that are expected to deliver properly packaged CSPs in an undamaged, sterile, and stable condition. Special handing instructions are provided and/or affixed to the exterior of the container when applicable.		

A designated person(s) follows up to ensure investigations are conducted and corrective actions are taken if problems, deviations, failures, or errors are identified or when complaints or adverse reactions are reported. A complete record of each reported complaint and adverse reaction is created and retained. Investigations and corrective actions are documented.		
A complete record of each reported complaint and adverse reaction is created and retained per USP 797.		
If CSPs are dispensed or administered before the results of release testing are known, procedures are in place to immediately notify the prescriber of a failure of specifications with a potential to cause patients harm; determine the severity of the problem and urgency for implementation/completion of recall; identify patients (or other points of distribution) who have received affected CSP; recall any unused dispensed CSPs; quarantine remaining stock in the pharmacy; investigate if other lots are affected and recalled if needed; conduct investigation and document reason for the failure.		
The overall QA/QC Program is reviewed at least once every 12 months by the Designated Person(s); the review is documented, and corrective actions are taken if needed.		
Documentation complies with all laws and regulations of the applicable regulatory jurisdiction. Records are legible and stored in a manner that prevents their deterioration and/or loss. All required documentation for a particular CSP is readily retrievable for at least 3 years after preparation.		

BUD Limits for Category 2 CSPs

(Circle the applicable preparation characteristics and storage conditions)

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed and Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (−25° to −10°)
Aseptically processed CSPs	No	Prepared from one or more nonsterile starting components: 1 day	Prepared from one or more nonsterile starting components: 4 days	Prepared from one or more nonsterile starting components: 45 days
		Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45 days
	Yes	30 days	45 days	60 days
Terminally Sterilized CSPs	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

BUD Limits for Category 3 CSPs

(Circle the applicable preparation characteristics and storage conditions)

Preparation Characteristics	Storage Conditions		
Compounding Method	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (−25° to −10°)
Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs	60 days	90 days	120 days
Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs	90 days	120 days	180 days

Are Beyond-Use Dates (BUDs) assigned appropriately?	Yes / No	Yes / No

Compounding Personnel and Competency Evaluation/Assessment

(If personnel have only taken & passed initial evaluation/assessment state "initial" otherwise state assessment dates)

NAME	LICENSE #	Annual Training and Competency Assessment of Core Skills	Garbing Competency Evaluation every 6 months (or 3 months if Category 3 CSPs made)	Aseptic Manipulation Competency Evaluation every 6 months (or 3 months if Category 3 CSPs made)