New Mexico Board of Pharmacy

CATEGORY 1 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 or Soaks for live organs or 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

INSPECTION CHECKLIST

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

I. SEGREGATED COMPOUNDING AREA (SCA)	Compliant? Yes/No/NA	COMMENTS
The SCA is dedicated to sterile compounding activities only. Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA, and they should be low-shedding and easily cleaned and disinfected. Their number, design, location, and manner of installation must not impact environmental air quality and must promote effective cleaning and disinfecting.		
The area within 1 m of the PEC should be dedicated only for sterile compounding (e.g., not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities such as patient care).		
SCA is not located near unsealed windows or doors that connect to the outdoors or high traffic flow.		
SCA is not adjacent to construction sites, warehouses or food preparation.		
No shipping carton(s) or other corrugated or uncoated cardboard are allowed in the SCA.		

Surfaces in the SCA should be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.		
Dust-collecting overhangs, such as utility pipes, and ledges, such as windowsills, should be minimized. If overhangs or ledges are present, they must be easily cleanable.		
C-SCA shall maintain a well-lighted work environment with an average of 80-150 foot candles.		
A hand-washing sink must be placed not closer than 1 m to the PEC and may be either inside the SCA or in close proximity to the SCA. Sinks should enable hands-free use.		
Carts in the SCA should be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility.		
*Trash receptacle at least 6 feet away from PEC – Best Practice		
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 SCA has been altered.		
Dynamic airflow smoke pattern testing is performed in all primary engineering controls under dynamic conditions initially and every 6 months to demonstrate unidirectional airflow and sweeping action over and away from the preparation. The airflow smoke patterns should be documented, ideally with video.		
HEPA filter leak tests is performed initially and every 6 months in primary engineering controls.		
Viable volumetric air sampling shall occur throughout all ISO areas using an impaction air sampler at least every 6 months for Category 1 CSPs. 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.		
Surface sampling shall be performed in all ISO classified areas at least monthly for **Category 1.** Sampling locations shall be defined in SOPs in a diagram or map.		

Viable air and surface samples did not exceed recommended USP action levels (or internal action levels if more restrictive). Classification Air Sample Surface Sample ISO Class 5 >1 CFU/m3 >3 CFU/plate CFUs are TOTAL of bacterial plus fungal/mold plates.		
An attempt is made to identify any microorganism recovered to the genus level when CFUs detected by air or surface sampling exceeded action levels.		
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.		

If turned off, the PEC shall be disinfected and allowed to operate for a minimum of 30 minutes before any sterile compounding takes place.		
Has the PEC been moved since last inspection (aside from routine cleaning)? If so, was it recertified?		
Incubators must not be placed in the SCA.		
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 SCA.		
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 (such as automated compounding devices) 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 one-step disinfectant cleaner or 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 the SCA. 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 SCAs are properly trained and gown and glove properly for all cleaning procedures (garbing order and guidelines same as for compounding).		
Floors in SCA 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 in the SCA 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 SCA for facilities compounding Category 1 CSPS. Ask for Log.		

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 1 CSPs must successfully complete a garbing competency evaluation with gloved fingertip testing at least one time every 6 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 1 CSPs must successfully complete an aseptic manipulation competency at least one time every 6 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 the SCA, staff shall remove outer garments, piercings, cosmetics, earbuds/headphones, and jewelry.		
Artificial nails, extenders and polish are not allowed in the SCA. Nails must be short and clean.		

Food (including gum and mints) and drinks are not allowed in the SCA.		
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.)		
Handwashing Procedures: • 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 low-lint disposable towels or wipers.		
Garb must be donned and doffed in an order that reduces the risk of contamination. Donning and doffing garb should not occur in the same area at the same time. PPE must include at least the following: • 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		
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 SCA in a manner that prevents contamination.		
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 1 CSPs from <u>nonsterile starting components</u>?	<u>Circle Answer</u>: Yes or No (if No, skip to letter **A**)	
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.		
If the PECs used for sterile and nonsterile compounding (e.g. presterilization procedures) are placed in the same room, they must be placed at least 1 meter apart, and particle-generating activity must not be performed when sterile compounding is in process.		

Personnel are garbed and gloved during pre-sterilization procedures the same as when performing compounding.		
Facility 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.		
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 1 CSPs <u>aseptically processed</u> (either compounded with only sterile starting ingredient(s) or compounded with nonsterile ingredient(s) followed by sterilization by filtration), or <u>terminally sterilized</u> (e.g., steam, dry heat, or irradiation)? <u>{Note: If one or more starting components being used to compound is not sterile, sterility must be achieved through sterilizing filtration or terminal sterilization}</u>	<u>Circle Answer</u>: Aseptically Processed (If sterilized by filtration go to **B**. below; if only sterile starting ingredients are used skip to **E** below) Terminally Sterilized (Skip to **C** and/or **D** below)	
B. Filtration (aseptically processed)		
If Category 1 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).		
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.		
E. 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?		
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. PRODUCT RELEASE/QUALITY CONTROL/QUALITY	Compliant? Yes/No/NA	COMMENTS

ASSURANCE		
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 1 CSPs

(Circle the applicable preparation characteristics and storage conditions)

Storage Conditions	
Controlled Room Temperature (20°–25°) ≤12 h	Refrigerator (2°–8°) ≤24 h
→ Are Beyond-Use Dates (BUDs) assigned appropriately?	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	Aseptic Manipulation Competency Evaluation every 6 months