New Mexico Board of Pharmacy
PRELIMINARY 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 plan to **dispense** patient-specific CSPs pursuant to a prescription?	Yes/No
Does the pharmacy plan to **distribute** CSPs without a prescription or compound sterile preparations for office use?	Yes/No
Does the pharmacy plan to dispense any CSPs out of New Mexico?	Yes/No
If so, to which states will CSPs be shipped?	
If CSPs are shipped out of state, does the pharmacy have policies and procedures for proper shipping?	Yes/No
What volume of CSPs will be shipped out of state? (If more than 5% of total prescriptions dispensed, the pharmacy must register as an outsourcing facility)	%
Does the pharmacy plan to 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 will be 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) will be 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.		

II. CERTIFICATION & DOCUMENTATION	Compliant? Yes/No/NA	COMMENTS
All Primary Engineering Controls are initially certified by an independent qualified contractor and maintain ISO Class 5 or better air quality during dynamic conditions.		
Dynamic airflow smoke pattern testing is initially performed in all primary engineering controls under dynamic conditions 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 test is performed initially in primary engineering controls.		
Viable volumetric air sampling shall be initially performed throughout all ISO areas using an impaction air sampler. 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 initially performed in all ISO classified areas. 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.		
Incubators must not be placed in the SCA.		

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.		
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.		

III. 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. (Check if one-step disinfectant cleaner/germicidal detergent available)		
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. (Check if sterile 70% IPA available)		
All cleaning materials are low-lint. Cleaning materials (sponges, wipers, mop heads) should be disposable. (Check if available)		

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. (Check if available)		
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. (Check if sporicidal agent is available.)		

IV. PERSONNEL CLEANSING AND GARBING	Compliant? Yes/No/NA	COMMENTS
The following is available for handwashing procedures: • Disposable nail cleaners • Low-lint disposable towels		
The following is available for Category 1 Garbing: • Low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gown or coverall) • Low-lint shoes covers • 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. (Check if available)		
Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA.		

V. ASEPTIC PROCESSING, TERMINAL STERILIZATION, AND MISC.	Compliant? Yes/No/NA	COMMENTS
Will the facility prepare Category 1 CSPs from nonsterile starting components?	Circle Answer: 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 have been certified initially.		
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.		
A. Are the Category 1 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 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. (Check if filters available)		

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. (Check if bubble-point test equipment available)		
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.		
Before filling containers to be steam sterilized, solutions are passed through a filter no larger than 1.2 µm to remove particulates. (Check if filters available)		
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. (Check if biological indicators are available)		
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). (Check if data recorder available)		
D. Terminal Sterilization by Dry Heat		
The terminal sterilization process is intended to achieve a probability of a nonsterile unit (PNSU) of 10−6.		

Before filling containers to be dry heat sterilized, solutions are passed through a filter no larger than 1.2 µm to remove particulates. (Check if filters available)		
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). (Check for temperature and time controls)		
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). (Check for biological indicators)		
E. Depyrogenation		
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.		
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. (Check if ECVs are available)		

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

(Direct oversight personnel must also initially complete training and demonstrate competency and also initially complete a garbing competency evaluation and aseptic manipulation competency evaluation.)

NAME	LICENSE #	Initial Training and Competency Assessment of Core Skills	Initial Garbing Competency Evaluation	Initial Aseptic Manipulation Competency Evaluation