STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797 USP Sterile Compounding

File #
Insp #

NAME	PERMIT NUMBER	DATE OF INSPECTION	
DOING BUSINESS AS			
STREET ADDRESS		TELEPHONE #	EXT
CITY	COUNTY	STATE/ZIP	

Additional Information

Business Operation Hours

Monday	Monday Hours
Tuesday	Tuesday Hours
Wednesday	Wednesday Hours
Thursday	Thursday Hours
Friday	Friday Hours
M-T-W-TH-F	Saturday N
Saturday Hours	Sunday N
Sunday Hours	

Registered Pharmacist / Intern / Tech

License #	Licensee Name
License Type	
License #	Licensee Name
License Type	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg #	

License Relations

Special Sterile Compounding

	License #

INV797 - USP Sterile Compounding (Revision 1, USP 797 2022. August 2024)

A. INTRODUCTION & SCOPE – ALL CATEGORIES

DESIGNATED PERSON: A designated person(s) is identified who is responsible and accountable for the performance and operation of the facility and personnel involved in the preparation of CSPs. [USP 797 Section 1.1.3]	
IMMEDIATE USE COMPOUNDING: When preparing immediate use preparations, written SOPs are in place for all requirements and all criteria are met including 1. aseptic technique, processes, and procedures; and, 2. personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and SOP's, 3. the preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs, 4. the preparation involves not more than 3 different sterile products, 5. Any unused starting component from a single-dose container is discarded, 6. Administration begins within 4 hours following the start of preparation and, 7. Unless directly administered by the preparer or administration is witnessed by the preparer, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the preparer and the 4-hour period within which administration must begin. [USP 797 Section 1.3]	
BAG & VIAL SYSTEM: Docking of vial and bag systems for future activation and administration is performed in an ISO 5 environment and BUDs are not longer than those specified in the manufacturer's labeling. [USP 797 Section 1.4]	

REPACKAGING: Repackaging of sterile products or preparations from its original container into another container are prepared according to all applicable USP 797 requirements. [USP 797 Section 1.1.2]	

B. COMPONENT BUDs (Single and Multi-dose Containers) – ALL CATEGORIES

SINGLE DOSE CONTAINERS (SDCs): SDCs are entered or punctured only in an ISO Class 5 or cleaner air and are used up to 12 hours after initial entry or puncture if the labeled storage requirements during that 12-hour period are maintained. [USP 797 Section 15.1]	
AMPULES: Opened SINGLE DOSE AMPULES are used immediately and not stored for any time period. [USP 797 Section 15.1]	
MULTIDOSE CONTAINERS (MDCs): Upon initially entering or puncturing a conventionally manufactured MDC, the MDC is not used for more than 28 days unless otherwise specified by the manufacturer on the labeling. [USP 797 Section 15.2]	
PHARMACY BULK PACKAGES: Conventionally manufactured pharmacy bulk packages are entered or punctured only in an ISO Class 5 PEC and must be used according to the manufacturer's labeling. [USP 797 Section 15.3]	
SINGLE DOSE COMPONENT CSPs & STOCK SOLUTIONS: When single-dose CSPs or CSP stock solutions are used as a component to compound additional CSPs, the original compounded single-dose component CSP or CSP stock solution is entered or punctured in ISO Class 5 or cleaner air and is stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). Once punctured, the component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter, and any remainder is discarded. [USP 797 Section 16.2]	

C. CSP LABELING – ALL CATEGORIES

CSP LABEL REQUIREMENTS: CSP Immediate container label prominently and legibly displays 1) assigned internal identification number; 2) active ingredient(s) and their amount(s), or concentration(s); 3) storage conditions if other than controlled room temperature; 4) BUD; 5) dosage form; 6) total amount or volume; 7) statement if CSP is a single dose container (when space permits) or multi-dose container. Labeling of CSP displays 1) route of administration, 2) special handling instructions, 3) warning statements, and the compounding facility name and contact information if the CSP is sent outside of the facility in which it was compounded. [USP 797 Section 13]	
ADDITIONAL REQUIREMENTS FOR A CLASS II OR III FACILITY: 1) Identification of responsible compounding personnel and/or dispensing pharmacist;2) labels for batch-prepared CSPs must also include: Control or lot number, auxiliary labeling (including precautions); and device-specific instructions. Patient specific medications must also include patient's name, location the medication is to be delivered to and directions for use. [USP 797 Section 13] [F.A.C.64B16-28.108(10)]	
LABELING SOP: SOPs describe labeling procedures and are followed to prevent labeling errors and CSP mix-ups. [USP 797 Section 13]	
LABEL VERIFICATION: CSP labels are verified to ensure that they conform with the prescription or medication order, MFR (if required), and the CR. [USP 797 Section 13]	

D. PERSONNEL PREPARATION & OBSERVATION – ALL CATEGORIES

UNNECESSARY ITEMS: Personnel remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); cosmetics, and all hand, wrist, and other exposed jewelry, including piercings that may interfere with effectiveness of garbing. Items not necessary for compounding (e.g., food, drinks, mints, gum, earbuds, headphones) are not introduced into the compounding environment. Accommodations are documented. [USP 797 Section 3.1]	
NAILS: Nails are clean and trimmed. Nail products (e.g., polish, artificial nails, and extenders) are not worn. Personnel clean under nails under warm running water with a disposable nail cleaner. Hands and forearms are washed with soap and water for at least 30 seconds prior to entering a compounding area. [USP 797 Section 3.2]	
REQUIRED PPE GARBING ORDER & STORAGE: Personnel garb (don and doff) in an order that reduces risk of contamination per SOP. Required garb, manner of storage, and order or garbing is documented in SOP's. The minimum required PPE when preparing CSPs includes a garment with sleeves that fit around wrists and enclosed neck, shoe covers, head/facial hair cover, face mask, and sterile powder-free gloves. All PPE is low lint for Category 1 & 2 compounding or sterile if Category 3. Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA. [USP 797 Section 3.3]	
INAPPROPRIATE HAND HYGIENE PRACTICES: Brushes and hand dryers are not used, and soap containers are not refilled or topped off. [USP 797 Section 3.2]	
ALCOHOL-BASED HAND RUB: Hands are sanitized with alcohol-based hand rub prior to donning gloves. Handrub is used prior to donning garb when hand hygiene is done outside of a classified area. [USP 797 Section 3.3]	
STERILE GLOVES USED: Sterile gloves are donned in classified room or SCA. Skin is not exposed inside ISO 5 PEC (e.g., gloves are not donned or doffed). [USP 797 Section 3.3]	
SANITIZATION OF STERILE GLOVES: Sterile 70% IPA is applied to gloves prior to compounding and regularly throughout the compounding process. [USP 797 Section 3.3]	
SANITIZATION OF ITEMS INTRODUCED INTO PEC: Items are wiped with sterile 70% IPA and sterile low-lint wipers just prior to being introduced into the PEC and allowed to dry before use. [USP 797 Section 8.2]	
CRITICAL SITES (e.g., vial stoppers, ampule necks, and intravenous bag septum's) are wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA is allowed to dry before personnel enter or puncture stoppers and septum's or break the necks of ampules. [USP 797 Section 8.3]	
MATERIALS AND EQUIPMENT DISINFECTION: Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. Dwell time is followed. [USP 797 Section 8.1 & 9.1]	

E. EQUIPMENT, SUPPLIES, & COMPONENTS – ALL CATEGORIES

DAILY ACD ACCURACY ASSESSMENT: An accuracy assessment is conducted for Automated Compounding Devices (ACDs) or similar equipment before the first use and again each day the equipment is used to compound CSPs. A daily record of accuracy measurements is maintained. Corrective actions are implemented if accuracy measurements are outside of manufacturer's specifications. [USP 797 Section 9.1]	
EQUIPMENT SOPs: Written SOPs for the calibration, maintenance, cleaning, and use of equipment are established and are based on the manufacturer's recommendations. Procedures are followed and records are maintained. [USP 797 Section 9.1]	

F. SEGREGATED COMPOUNDING AREA: Category 1

CATEGORY 1 MAXIMUM BUDs & COMPOUNDING AREA REQUIREMENTS: Category 1 CSPs are compounded in an ISO class 5 PEC located within a SCA and are assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less when refrigerated. [USP 797 Section 1.5, 4.2.1]	
DEDICATED AREA FOR SCA: The SCA is separated from areas not directly related to compounding, and all surfaces (walls, floors, counters, and equipment) are clean, uncluttered, and dedicated to compounding. [USP 797 Section 4.2.1]	

SCA LOCATION: The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC. SCA is not located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA. A sink is not located within 1 meter of PEC. [USP 797 Section 4.2.1]	
ITEMS WITHIN SCA: Only furniture, equipment, and other materials necessary for performing compounding activities are located within the SCA. [USP 797 Section 4.2.1]	

G. FACILITIES & SECONDARY ENGINEERING CONTROLS – Categories 2 and 3

STERILE SUITE CONSTRUCTION: The ISO-classified anteroom and buffer room are separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls are in place. [USP 797 Section 4.2.1]	
HEPA FILTERED AIR: Air supplied to the cleanroom suite is introduced through HEPA filters located in the ceiling of the buffer room and anteroom. [USP 797 Section 4.2.1]	
AIR RETURNS: Air returns in the cleanroom suite are low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. [USP 797 Section 4.2.1]	
LINE OF DEMARCATION: The anteroom has a line of demarcation to separate the clean side from the dirty side. [USP 797 Section 4.2.1]	
SURFACES & WALLS: The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area are smooth, impervious, free from cracks and crevices, and non-shedding. Walls are constructed of/or covered with durable material. [USP 797 Section 4.3.1]	
CEILINGS & FLOORS: Inlaid panels of ceilings are caulked around each panel to seal them to the support frame. Junctures between the ceiling and the walls and between the walls and the floor are sealed to eliminate cracks and crevices where dirt can accumulate. Floors include coving to the sidewall, or the juncture between the floor and the wall are caulked. [USP 797 Section 4.3.1]	
LEDGES & OVERHANGS: Overhangs and ledges are easily cleanable, and the exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed. [USP 797 Sections 4.3.1]	
FURNITURE, EQUIPMENT, & MATERIALS: Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. Tacky mats are not placed within ISO-classified areas. Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels. [USP 797 Sections 4.2.1 & 4.5]	
TEMPERATURE & HUMIDITY MONITORING: Temperature and humidity in the cleanroom suite are controlled through a heating, ventilation, and air conditioning (HVAC) system. The temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. They are documented at least once daily or stored in the continuous recording device and are retrievable and are reviewed as described in the facility's SOP. [USP 797 Section 4.2]	
PRESSURE DIFFERENTIATION MONITORING & DOCUMENTATION: Facility maintains a minimum differential positive pressure of 0.020-inch water column between the nonhazardous buffer room to anteroom and anteroom to unclassified area. A pressure differential monitoring device is used to continuously monitor the pressure differentials. Quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding is occurring. [USP 797 Sections 4.2.5]	
PEC LOCATION: PECs are located in a buffer room in a manner that minimizes conditions that could increase the risk of microbial contamination (strong air currents, personnel traffic, or air streams from HVAC system(s)) and allows for cleaning around the PEC. [USP 797 Sections 4.2.2 & 4.2.3]	
INTEGRATED VERTICAL LAMINAR FLOW ZONES: IVLFZ is separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface. [USP 797 Section 4.2.3]	

H. CERTIFICATION AND RECERTIFICATION – ALL CATEGORIES

PEC & SEC CERTIFICATION: PECs are certified initially and every 6 months to meet ISO Class 5 or better conditions, during dynamic operating conditions. SECs are certified initially and every 6 months to meet ISO Class 7 or 8 or better conditions, during dynamic operating conditions (including presterilization activities if applicable). Anterooms providing access to positive-pressure buffer rooms are at least ISO 8 and at least ISO 7 for anterooms providing access to negative-pressure buffer rooms. ISO Class 7 rooms maintain a minimum of 30 total HEPA-filtered ACPH during dynamic operating conditions, at least 15 ACPH come from the HVAC through HEPA filters located in the ceiling. ISO Class 8 rooms maintain a minimum of 20 total HEPA-filtered ACPH during dynamic operating conditions; 15 ACPH must come from the SEC. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH are documented on the certification report. HEPA filter integrity testing for both SECs & PECs is conducted initially and every 6 months as part of total particle testing. Classified areas are recertified when changes occur that could affect airflow or air quality [USP 797 Sections 4.1, 4.2.4, 4.2.6, & 5.0]	
DOCUMENTATION OF PERSONNEL PRESENT DURING CERTIFICATION: The number of personnel present in each PEC and SEC during total particle counts and dynamic airflow smoke-pattern tests is documented on the certification report. [USP 797 Section 5.0]	
PEC DYNAMIC SMOKE PATTERN TEST: Smoke pattern tests are performed under dynamic conditions initially to demonstrate minimal disruption in airflow and repeated if equipment is placed in a different location. Smoke pattern tests are performed under dynamic conditions every 6 months to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). [USP 797 Section 5.0]	
ROBOTICS / ROBOTIC ENCLOSURES: Robotic enclosures used as a PEC or placed within a PEC have a dynamic airflow smoke pattern test is performed initially and at least every 6 months that confirms 1) the robotic device is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s). [USP 797 Section 4.2.3]	
MONITORING DEVICE CERTIFICATION: Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. [USP 797 Section 4.2]	
CONTAINMENT DEVICES USED FOR PRESTERILIZATION PROCEDURES: CVEs, BSCs, or CACIs used for presterilization procedures are certified at least once every 6 months. Presterilization procedures do not adversely affect the required air quality of the SEC as demonstrated during certification under dynamic operating conditions. [USP 797 Section 4.2.6]	
CERTIFICATION REPORT REVIEW BY DESIGNATED PERSON: 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. [UPS 797 Section 5.0]	

I. RABS

LOCATION: If used to prepare Category 2 or Category 3 CSP's RABS are located in a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. [USP 797 Section 4.2.3]	
RECOVERY TIME: 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. [USP 797 Section 4.2.3]	
STERILE GLOVES: are worn over gloves attached to RABS sleeves. [USP 797 Section 3.3]	

J. CATEGORY 2 CSPs WITHOUT STERILITY TESTING

CATEGORY 2 COMPOUNDING ENVIRONMENT: Category 2 CSPs are compounded in an ISO class 5 PEC located within an ISO classified anteroom and buffer room. [USP 797 Sections 4.1 & 14.3]	
CATEGORY 2 BUDs FROM STERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from all sterile starting components and in the absence of sterility testing do not exceed the following BUDs: 4 days room temperature, 10 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FROM NONSTERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from one or more nonsterile starting components and in the absence of sterility testing do not exceed the following BUDs: 1 day room temperature, 4 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3]	

K. CATEGORY 2 EXTENDED BUD REQUIREMENTS

CATEGORY 2 BUDs FOR ASEPTICALLY PROCESSED CSPs WITH STERILITY TESTING: Category 2 CSPs compounded aseptically, and which have passed sterility testing do not exceed the following BUDs: 30 days room temperature, 45 days refrigerated, or 60 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITHOUT STERILITY TESTING: Category 2 CSPs terminally sterilized and in the absence of sterility testing do not exceed the following BUDs: 14 days room temperature, 28 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITH STERILITY TESTING: Category 2 CSPs terminally sterilized, and which have passed sterility testing do not exceed the following BUDs: 45 days room temperature, 60 days refrigerated, or 90 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmics) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved CSPs), container integrity testing is performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are assigned are prepared as a Category 2 CSP, for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	
OUTSOURCED STERILITY TESTING: Sterility testing is performed for all Category 2 CSPs assigned a BUD requiring sterility testing according to USP <71> or a validated alternative and noninferior method. Membrane Filtration as described in USP <71> is the preferred method when the formulation allows. [USP 797 Section 12.2]	
INHOUSE STERILITY TESTING: 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. (2 incubators present).	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method. [USP 797 Section 12.2]	
MAXIMUM BATCH SIZE: The maximum batch size for all CSPs requiring sterility testing is 250 final yield units. [USP 797 Section 12.2]	
INVESTIGATION OF STERILITY TEST FAILURES: 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. [USP 797 Section 12.2]	
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: 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. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: 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. [USP 797 Section 12.3]	

L. CATEGORY 3 CSPs, BUDs, & RELATED REQUIREMENTS

CATEGORY 3 REQUIREMENTS: All requirements associated with Category 3 compounding (e.g., garbing, cleaning, environmental monitoring) apply to all personnel entering the buffer room where Category 3 CSPs are compounded and always apply regardless of whether Category 3 CSPs are compounded on a given day. [USP 797 Section 14.4.2]	
STERILE/SINGLE USE GARB: When compounding Category 3 CSPs, skin is not exposed in buffer room (i.e., face and neck are covered) and all low lint outer garb is sterile, including sterile sleeves over RABS gauntlet sleeves. Disposable garb items are not reused. [USP 797 Section 3.3]	
STERILIZED/REUSABLE GARB: Non-disposable garb is not reused without being laundered and resterilized with a validated cycle. Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment. [USP 797 Section 3.3]	
CATEGORY 3 BUDs FOR ASEPTICALLY PROCESSED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 60 days room temperature, 90 days refrigerated, or 120 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for aseptically processed CSPs. [USP 797 Section 14.4.3]	
CATEGORY 3 BUDs FOR TERMINALLY STERILIZED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 90 days room temperature, 120 days refrigerated, or 180 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for terminally sterilized CSPs. [USP 797 Section 14.4.3]	
MAXIMUM BATCH SIZE: Category 3 CSP batch sizes do not exceed 250 final yield units. [USP 797 Section 12.2]	

STABILITY INDICATING ASSAYS: All Category 3 CSP formulations are supported by data obtained using a validated stability-indicating analytical method that can distinguish active ingredients from degradants and impurities and quantify the amount of active ingredient. CSPs are prepared according to the exact formulation, components, and packaged in a container closure system of the same materials of composition. Facilities have documentation of the stability study, its results, and the method validation available for review. [USP 797 Section 14.3.3]	
STERILITY TESTING: All category 3 CSPs and batches undergo sterility testing performed according to USP <71> or a validated alternative and noninferior method. [USP 797 Sections 12.2 & 14.4.4]	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method for each formulation. [USP 797 Section 12.2]	
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: 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. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	
INVESTIGATION OF STERILITY TEST FAILURES: 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. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 3 injectable CSPs compounded from one or more nonsterile component(s) are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: 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. [USP 797 Section 12.3]	
PARTICULATE MATTER TESTING: Category 3 injectable CSPs undergo USP <788> (Particulate Matter in Injections) and ophthalmic solutions undergo USP <789> (Particulate Matter in Ophthalmic Solutions) test once per formulation with acceptable results. [USP 797 Section 14.3.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmic) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved multi-dose CSPs), container closure integrity testing is also performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are prepared for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	

M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

TRAINING PROGRAM & SOP: Facility maintains a written training program and corresponding SOP which defines required trainings, frequency of training and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification and dispensing of CSP's. The training program equips personnel with the appropriate knowledge and training in the required skills necessary to perform their assigned tasks. [USP 797 Section 2]	
INITIAL DIDACTIC TRAINING & SKILLS ASSESSMENT: Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel complete training and can demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. [USP 797 Section 2.1]	
INITIAL GLOVED FINGERTIP & HAND HYGIENE/GARBING COMPETENCY: Before beginning to compound independently or have direct oversight of compounding personnel, personnel successfully complete an initial gloved fingertip (GFT) competency no fewer than 3 separate times, with a documented visual audit while performing hand hygiene and garbing procedures. GFT samples are collected before applying sterile 70% IPA to gloves. [USP 797 Section 2.2]	
INITIAL MEDIA FILL & ASEPTIC TECHNIQUE ASSESSMENT: Before beginning to compound independently or have direct oversight of compounding personnel, personnel who compound or have direct oversight of compounding successfully complete an initial aseptic manipulation competency evaluation which 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. [USP 797 Section 2.3]	
GFT & MEDIA FILL INCUBATION: Documentation includes the name of the person evaluated, evaluation date and time, media and components used to include their manufacturer or supplier, expiration dates and lot numbers, starting temperature for each interval of incubation, dates of incubation, the results, and the names or other identification of the observer and the person who reads and documents the results. [USP 797 Section 2.3]	
ONGOING CATEGORY 1 AND 2- GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency evaluation and GFT every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	
ONGOING CATEGORY 1 AND 2- MEDIA FILL & ASSESSMENT: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months. GFTs and surface samples are appropriately incubated. [USP 797 Section 2.3]	
ONGOING KNOWLEDGE & COMPENTENCY OF CORE SKILLS: Training and knowledge assessment of sterile compounding principles or core skills is completed at least every 12 months. [USP 797 Section 2.1]	
FAILED COMPETENCY INVESTIGATION: Initial and ongoing competency assessment failures are investigated, remediated, and documented in a Corrective Action Plan. [USP 797 Sections 2.2 & 2.3]	
STAFF TRAINING IN VIABLE AIR AND SURFACE SAMPLING: Personnel are trained and competent in air and surface sampling procedures to ensure accurate and reproducible sampling. [USP 797 Section 6.1]	
CLEANING PERSONNEL: Cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures. Cleaning personnel demonstrate knowledge and competency of core skills related to cleaning, disinfection, and maintenance of environmental conditions initially and at least once every 12 months. [USP 797 Sections 7 & 2.1]	

FACILITY COMPOUNDS CATEGORY 3

ONGOING CATEGORY 3 GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency and GFT every 3 months for Category 3 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	

ONGOING CATEGORY 3 ASEPTIC PROCESSING COMPETENCY: Aseptic competency is repeated at least one time every 3 months for personnel compounding Category 3 CSPs. The simulation must capture elements that could potentially affect the sterility of the CSP. Immediately following the media-fill test, gloved fingertip and thumb sampling is performed on both hands and surface sampling of the direct compounding area. Direct oversight personnel who do not compound must complete media fill every 12 months. [USP 797 Section 2.3]	

N. MICROBIOLOGICAL AIR AND SURFACE MONITORING: ALL CATEGORIES

ENVIRONMENTAL MONITORING PROGRAM & SOPs: The microbiological air and surface monitoring program is clearly described in the facility's SOPs, which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that trigger corrective action. [USP 797 Section 6]	
VIABLE AIR SAMPLING: Volumetric active air sampling using an impaction air sampler collecting at least 1000L of air is conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions and is completed at least every 6 months. [USP 797 Section 6.2]	
AIR IMPACTION DEVICE: Device is serviced and calibrated according to the manufacturer's recommendations. [USP 797 Section 6.1]	
SURFACE SAMPLING: Microbiological surface sampling is conducted in all classified areas and pass-through chambers under dynamic operating conditions and performed at least once monthly. [USP 797 Section 6.3]	
GROWTH MEDIA: A general microbiological growth media that supports the growth of bacteria and fungi is used and a COA from the manufacturer is available. Growth media used for surface sampling contains neutralizing agents (e.g., lecithin and polysorbate 80). [USP 797 Sections 6.2 & 6.3]	
MEDIA INCUBATION: Samples are incubated at 30°C - 35°C for 48 hours and 20°C - 25°C for an additional 5 days; if dual growth media are used, incubate one media device at 30°C - 35°C for 48 hours and the second media device at 20°C - 25°C for 5 days. The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and results are reviewed and documented as described in the facility's SOPs. Incubators are placed in a location outside of the sterile compounding area. [USP Sections 6.2.2 (Box 5) & 6.3.2 (Box 6)]	
ENVIRONMENTAL MONITORING TREND ANALYSIS: Regular review of sampling data is performed to detect trends and review of trending data is documented. [USP 797 Section 6.1]	
CORRECTIVE ACTION: When microbial growth exceeds action levels, the cause is investigated, and corrective action is taken; corrective actions taken are reviewed for effectiveness. An attempt to identify microorganisms at the genus level is made. [USP Sections 6.2.3 & USP 6.3.3]	

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-VIABLE AIR SAMPLING: Volumetric air sampling is completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.Air sampling sites are selected in all classified areas. [USP 797 6.2.1]	
CATEGORY 3-SURFACE SAMPLING: Surface sampling for any Category 3 CSPs, is completed in all classified areas, and pass-through chambers connecting to classified areas, prior to assigning a BUD longer than BUD limits for Category 2 CSPs (defined in Table 13 of USP 797) and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. [USP 797 6.2.2]	
CATEGORY 3-BATCH SURFACE SAMPLING: 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. When a self-enclosed robotic device is used as the PEC, surface sampling is conducted at least once daily at the end of compounding operations before cleaning and disinfection occurs. [USP 797 Section 6.3.2]	

O. CLEANING AND DISINFECTING: ALL CATEGORIES

CLEANING SOPS: The frequency, method(s), documentation requirements, and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants are described in written SOPs; use of agents is in accordance with manufacturer's instructions, procedures, and in adherence with minimum wet contact times. SOPs describe the time period during which, once opened, sterile cleaning and disinfecting agents, supplies, and sterile 70% IPA may be reused. Sterile water is used to dilute concentrated cleaning agents used inside of PECs (if applicable). Cleaning and disinfecting agents are EPA-registered. If a one-step disinfectant cleaner is not used, surfaces are cleaned prior to being disinfected. [USP 797 Section 7]	
DAILY PEC CLEANING & DISINFECTION WITH STERILE AGENTS: Equipment and all interior surfaces of the PEC are cleaned and disinfected daily on days when compounding occurs and when surface contamination is known or suspected. Sterile 70% IPA is applied after cleaning, disinfecting, or after one-step disinfectant cleaner or sporicidal agent application to remove residue. [USP 797 Section 7]	
CATEGORY 1 AND 2-MONTHLY PEC SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, are cleaned with a sporicidal agent monthly. [USP 797 Section 7]	
DAILY SEC & SCA CLEANING & DISINFECTION: Work surfaces, floors, sink surfaces, and pass-through chambers are cleaned and disinfected daily on days when compounding occurs. [USP 797 Section 7]	
CATEGORY 1 AND 2 -MONTHLY PEC, SEC & SCA SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings*, walls, doors, and doors frames at least once monthly. SCA ceilings (if applicable) are only cleaned, disinfected, and have sporicidal agents applied when visibly soiled and when surface contamination is known or suspected. [USP 797 Section 7]	
PEC SANITIZATION WITH STERILE 70% IPA: Sterile 70% IPA is applied to the horizontal work surface, including removable trays, immediately before initiating compounding and at least every 30 minutes. If a compounding process takes more than 30 minutes, the work surface is disinfected immediately after the end of the compounding process. Sterile 70% IPA is allowed to dry. [USP 797 Section 7]	
CLEANING SUPPLIES & TOOLS: All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), except for tool handles and holders, are low lint. Supplies used inside PECs are sterile. [USP 797 Section 7.1.2]	
REUSABLE CLEANING TOOLS: Reusable cleaning tools (e.g., mop frames) are made of cleanable materials and are cleaned and disinfected before and after each use. Reusable tools are dedicated for use in the classified areas or SCA and are not removed. Mops used in HD compounding areas, are dedicated for use only in those areas. [USP 797 Section 7.1.2]	

FACILITY COMPOUNDS CATEGORY 3

WEEKLY SPORICIDAL CLEANING OF PECs & SECs: Weekly cleaning using a sporicidal agent is performed on all internal surfaces of PEC and equipment in PEC's, on work surfaces outside the PEC, pass-through chambers, and floors. [USP 797 Section 7]	
MONTHLY SEC SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to storage shelving and bins, equipment outside of PEC's, sink surfaces, ceilings, walls, doors, and doors frames at least once monthly. [USP 797 Section 7]	

P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

PRESTERILIZATION ACTIVITY CONTAINMENT ENCLOSURES: Pre-sterilization procedures, such as weighing and mixing of nonsterile components, occur in ISO Class 8 or better environment (e.g., anteroom or buffer room) and are performed in single-use containment glove bags, CVEs, BSCs, or CACIs. [USP 797 Section 4.2.6]	
LOCATION OF STERILE & NONSTERILE PECs: 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 [USP 797 Section 4.2.1; USP 800 Section 5.3]	
COMPONENT SOPs: Written SOPs address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components including ingredients and container closures. [USP 797 Section 9.3]	
COMPONENT QUALITY & COA: APIs and components comply with the criteria in the USP-NF (if one exists for inactive components) and have a COA including specifications and test results showing the API or component meets expected quality. APIs and other components labeled “not for pharmaceutical use”, “not for injectable use”, “not for human use”, or equivalent are not used in CSPs. [USP 7 Section 9.3.1]	
API MANUFACTURERS: APIs are manufactured by an FDA-registered facility in the U.S. or comply with the laws and regulations of the applicable regulatory jurisdictions outside of the U.S. [USP 797 Section 9.3.1]	
COMPONENT STORAGE: Components 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. [USP 797 Section 9.3.4]	
STERILE, DEPYROGENATED SUPPLIES: Supplies in direct contact with CSPs are sterile and depyrogenated. A COA or similar conformance documentation is reviewed. [USP 797 Section 9.3.1]	
COMPONENT RECEIPT: Upon receipt, the external packaging of components is examined and components of unacceptable quality or showing deterioration are promptly labeled as rejected and segregated from active stock. APIs and components are inspected for a visible manufacturer expiration date. Components lacking expiration dates are assigned an expiration date no more than 1 year after receipt and both the date of receipt and facility assigned expiration date is clearly marked on the component packaging. [USP 797 Section 9.3.2]	
STERILIZATION OF INJECTABLES WITHIN 6 HOURS OF COMPLETION: Injectable CSPs containing nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during compounding are sterilized within 6 hours of completion. [USP 797 Section 10]	

Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

STERILIZING FILTERS: Sterilizing filters used are sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and are appropriate for pharmaceutical use. Sterilizing filters are certified by the manufacturer to retain at least 10,000,000 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area. Filters are chemically and physically compatible with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity); chemically stable at the pressure and temperature conditions that will be used; and have enough capacity to filter the required volumes. [USP 797 Section 10.2]	
BUBBLE POINT TESTING: Sterilizing filters are subjected to the manufacturers’ recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters passes a filter-integrity test. [USP 797 Section 10.2] For failed BP testing, CSP is discarded or, after investigating, refiltered not more than one time. [USP 797 Section 10.2]	
CSP PREFILTRATION: When CSPs are known to contain excessive particulate matter, prefiltration is performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of (i.e., prior to) the sterilizing filter. [USP 797 Section 10.2]	
CSP TERMINAL STERILIZATION SOP includes: 1) A description of CSP terminal sterilization process(es), including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization methods and equipment. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10]	
STEAM OR DRY HEAT STERILIZATION CYCLES FOR CSPs: 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. CSPs sterilized vial steam are placed in the autoclave to allow steam to reach CSPs without entrapment of air. CSPs sterilized via dry heat are placed with sufficient space between materials to allow for hot air circulation. Sterilization cycle parameters (e.g., temperature, pressure, and duration) and load configuration(s) are documented. [USP 797 Section 10.3 & 10.4]	
BIOLOGICAL INDICATOR USE: The effectiveness of steam or dry heat sterilization of CSPs is verified and documented for each sterilization run or load by using appropriate biological indicators (e.g., Geobacillus stearothermophilus for steam, Bacillus atrophaeus for dry heat) and other confirmation methods. [USP 797 Section 10.3]	
STEAM & DRY HEAT CSP PREFILTRATION: Immediately before filling containers that will be sterilized via steam, or dry heat, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.3]	
CALIBRATED DATA RECORDER: A calibrated data recorder or chart is used to monitor each steam or dry heat sterilization cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). The calibrated oven is equipped with temperature controls and a timer. [USP 797 Section 10.3 & 10.4]	

R. STERILIZATION & DEPYROGENATION OF SUPPLIES & CONTAINER CLOSURE SYSTEMS - CATEGORY 2 & 3

STERILIZATION & DEPYROGENATION SOP's include: 1) A description of sterilization and depyrogenation process(es) used to sterilize and/or depyrogenated compounding supplies and container closure systems, including the temperature, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10]	
DEPYROGENATION VIA DRY HEAT: 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. [USP 797 Section 10.1 & USP 1228.4]	
DEPYROGENERATION VIA RINSING: Non-thermostable items are sterilized via a validated sterilization method and cycle: these items are also 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. [USP 797 Section 10 & 10.1]	
DEPYROGENATION PROCESS VALIDATION: The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using Endotoxin Challenge Vials (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 cycle parameters. Cycle verifications are documented. [USP 797 Section 10.1]	
STERILIZATION CYCLE VALIDATION: When performed onsite, the efficacy of sterilization cycles used for supplies or container closure systems are established and documented. Each sterilization run or load is verified and documented by using appropriate biological indicators (e.g., spores of Geobacillus stearothermophilus) and other confirmation methods. [USP 797 Section 9.3.1 & USP 1229]	

S. MASTER FORMULATION AND COMPOUNDING RECORDS – ALL CATEGORIES

MASTER FORMULATION RECORD (MFR): A MFR is created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient and any changes or alterations to an MFR are approved and documented per facility's SOPs. [USP 797 Section 11.1]	
MFR DOCUMENTATION: An MFR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Identities, amounts of all ingredients, and, if applicable, relevant characteristics of components; 3) Type and size of container closure system(s); 4) Complete instructions for preparing the CSP including equipment, supplies, a description of the compounding steps, and any special precautions; 5) Physical description of the of the final CSP; 6) BUD and storage requirements; 6) Stability reference; 7) Quality control procedures; 8) other information as needed to describe the compounding process and ensure repeatability. [USP 797 Section 11.1 (Box 9)]	
COMPOUNDING RECORD (CR): A CR is created for all Category 1, Category 2, and Category 3 CSPs. A CR is created for immediate-use CSPs prepared for more than one patient. A CR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Date and time of preparation of the CSP; 3) Assigned internal identification number (e.g., prescription, order, or lot number); 4) A method to identify the individuals involved in the compounding process and individuals verifying the final CSP; 5) Name of each component; 6) Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s); 7) Weight or volume of each component; 8) Strength or activity of each component; 9) Total quantity compounded; 10) Final yield; 11) Assigned BUD and storage requirements; 12) Results of QC procedures. And, if applicable, 13) MFR reference for the CSP; and 14) Calculations made to determine and verify quantities and/or concentrations of components. [USP 797 Section 11.2]	
STERILIZATION CYCLE DOCUMENTATION: The date, run, and load numbers of the steam or dry heat sterilizer used to sterilize a CSP are documented on the CR if applicable. [USP 797 Sections 10.3 & 10.4]	

T. RELEASE INSPECTION AND TESTING – ALL CATEGORIES

RELEASE TESTING PROCEDURES: All release testing procedures (e.g., visual inspections and testing) are included in facility documentation such as MFRs and SOPs. [USP 797 Section 12]	
VISUAL INSPECTION: CSPs are visually inspected before release and dispensing to determine whether the 1) physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects), 2) container closure integrity is intact (e.g., checking for leakage, cracks in the container, or improper seals), 3) CSP and its labeling match the prescription or medication order. [USP 797 Section 12.1]	
DELAYED DISPENSING VISUAL INSPECTION: 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. [USP 797 Section 12.1]	
CSP REJECTION & QUARANTINE: CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock. [USP 797 Section 12.1]	
INVESTIGATION OF OOS RESULTS: 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. [USP 797 Section 12 & 12.1]	

U. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, & TRANSPORT – ALL CATEGORIES

STORAGE AREA TEMPERATURE MONITORING: Temperature in CSP & component storage areas is 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. Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months. When CSPs have been exposed to temperature excursions above or below storage temperature limits for the CSP, a Designated Person determines whether the CSP has retained its integrity or quality. [USP 797 Sections 9.3 & 19.1]	
CSP PACKAGING: CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption and prevent inadvertent exposure to transport personnel. [USP 797 Section 19.2]	
SHIPPING & TRANSPORTING: 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. [USP 797 Section 19.2]	

V. STERILE QUALITY PROGRAM, SOP's & DOCUMENTATION- ALL CATEGORIES

QA/QC PROGRAM & SOPs: A Quality Assurance (QA) and Quality Control (QC) program is documented in facility SOPs and formally establishes a system of 1) adherence to procedures, 2) prevention and detection of errors and other quality problems, 3) evaluation of complaints and adverse events, and 4) appropriate investigations and corrective actions. The QA/QC SOPs describe the roles, duties, and training of personnel responsible for each aspect of the QA program. [USP 797 Section 18]	
INVESTIGATIONS & CAPAs: 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. [USP 797 Sections 17, 18.2, & 18.3]	
ADR & COMPLAINT DOCUMENTATION: A complete record of each reported complaint and adverse reaction is created and retained per USP 797. [USP 797 Section 18.1]	
RECALL PROCEDURES & SOP: 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. Recalls are reported to the appropriate regulatory body as required by the laws and regulations of the applicable regulatory jurisdiction. [USP 797 Section 18]	
ANNUAL SOP & QA/QC COMPLIANCE REVIEW: Facility sterile compounding SOPs are reviewed every 12 months by the Designated Person(s); the review is documented. Changes to SOP are made only by the Designated Person and documented. Acknowledgement of revisions to SOP's are communicated to all personnel. 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. [USP 797 Section 17 & 18]	

W. HAZARDOUS DRUG HANDLING & COMPOUNDING – ALL CATEGORIES

DESIGNATED PERSON: The entity has a Designated Person who is qualified and trained to be responsible for implementing appropriate HD procedures, overseeing compliance with USP 800 requirements, ensuring environmental control of the storage and compounding areas, monitoring HD facility operations, testing, and acting on results. [USP 800 Section 4]	
HAZARD COMMUNICATION PROGRAM (HCP): Facility has SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of HDs and use of Safety Data Sheets. The HCP and HD SOPs include a written plan describing 1) how USP 800 requirements are implemented, 2) HD chemical container labeling with the identity of the material and appropriate hazard warnings, 3) readily accessible location of HD chemical SDSs known and accessible by all personnel, 4) HD risk training and information provided to all personnel with HD exposure risk before initial HD handling work assignment and whenever hazard changes, 5) personnel of reproductive capability written acknowledgement of understanding of HD handling risks. [USP 800 Section 8]	

LIST OF HAZARDOUS DRUGS & ASSESSMENT OF RISK: Facility maintains a list of HDs that includes any items on the current NIOSH that the entity handles. The list is reviewed every 12 months and whenever a new agent or dosage form is used. All HD drugs follow the requirements of USP 800 unless an assessment of risk (AOR) is performed. If an assessment of risk approach is taken, the entity must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. The AOR minimally contains the type of HD, dosage form, risk of exposure, packaging, and manipulation considerations. The HD drug list & AOR is reviewed at least every 12 months and whenever a new agent or dosage form is used. [USP 800 Section 2]	
CONTAINMENT REQUIREMENTS: All antineoplastic HDs requiring manipulation and HD active pharmaceutical ingredients (APIs) on the NIOSH list follow all the requirements of USP 800. [USP 800 Section 2, Box 1]	
HD HANDLING, RECEIPT & STORAGE SOPs: SOPs are created and followed for the safe handling of HDs used by the facility. [USP 800 Section 17]	
HD HANDLING AREAS, SIGNAGE, & ACCESS: Signage designating HD handling areas are prominently displayed and access to HD handling areas is restricted to authorized personnel. Designated areas are available for receipt, unpacking, storage, and sterile compounding of HDs. [USP 800 Section 5]	
HD STORAGE: HDs are stored to prevent spillage or breakage, off floors, and in areas appropriate for natural disasters. Antineoplastic HDs and HD API are stored separately from non-HDs to prevent contamination and personnel exposure. HD storage areas are externally ventilated and negative-pressure rooms with at least 12 ACPH. Refrigerated antineoplastic HDs are stored in a dedicated refrigerator, in a negative pressure area with at least 12 ACPH. Pass through refrigerators are not used. [USP 800 Section 5.2]	
STERILE HDs COMPOUNDED IN A C-SCA: C-SCA maintains a minimum of 12 ACPH of HEPA- filtered air and has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800, sections 5.3.2 Table 3]	
C-SEC DESIGN AND ENGINEERING CONTROLS: The C-SEC has fixed walls physically separated from other preparation areas, is externally ventilated has 30 ACPH, and negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800 Section 5.3.2 Table 3]	
C-SEC ACCESS: The Ante Room used for entry into the negative pressure buffer room has fixed walls and maintains a minimum of 30 ACPH of HEPA-filtered air, positive pressure of +0.02" w.c. to all adjacent unclassified areas, and ISO7 or better classification. Alternatively, a negative-pressure HD buffer entered exclusively through a positive pressure non-HD buffer room contains a line of demarcation (LOD) within the negative-pressure buffer room for donning/doffing HD PPE and a method a transport of HDs, HD CSPs, and HD waste into and out of the HD buffer (e.g., pass-through chamber). Pass through chambers are included in semi-annual facility certification. [USP 800 Section 5.3.2]	
C-SEC SINK & SAFETY EQUIPMENT: A sink is available for hand washing and an eyewash station and/or other emergency safety precautions meeting applicable laws and regulations are readily available and located where operation does not interfere with ISO classifications. Sinks are located at least 1 meter from the entrance into the buffer room (or at least 1 meter from the C-PEC in a C-SCA). [USP 800 Sections 5.3 & 5.3.2]	
C-PEC LOCATION, VENTING, & OPERATION: All C-PECs used for sterile HD compounding (e.g., CACIs or BSCs), are located within a C-SEC or C-SCA, externally vented, and maintain an ISO 5 or better air quality. C-PECs operate continuously if supplying some or all the negative pressure in the C-SEC or if used for sterile compounding. During power outages, repairs, or relocation, C-PEC use is suspended immediately. Once C-PEC power is restored, all PEC surfaces are decontaminated, cleaned, and disinfected, and compounding is not resumed until the manufacturer's specified recovery time has elapsed. [USP 800 Section 5.3.2]	
REQUIRED HD PPE: When compounding HDs, gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are donned per facility SOPs. Chemotherapy gloves are tested to ASTM standard D6978 (or its successor) and are powder free and two pair of chemotherapy gloves are donned per SOP. Gloves are inspected for physical defects. Gloves are changed when torn, punctured, or contaminated. Personnel wash hands with soap and water after removing gloves. HD gowns are disposable, resistant to permeability by HDs, close in back, are long sleeved, closed cuff, and seamless. Gowns are changed per manufacturer's permeation information; if no data is available, HD gowns are change every 2-3 hours or immediately after a spill or splash. Gowns are limited to HD handling areas and are donned over the sterile compounding garment. When compounding, a second pair of shoe covers is donned before entering the C-SEC and doffed when exiting the C-SEC. HD PPE is disposed of appropriately prior to exiting the C-SEC. Chemotherapy gloves and sleeve covers (if used during compounding) are carefully removed and discarded immediately into an appropriate waste container inside of the C-PEC or contained in a sealable bag for discarding outside of the C-PEC. Reusable PPE is decontaminated and cleaned after each use. [USP 800 Section 7]	
EYE AND FACE PROTECTION: Appropriate eye (goggles) and face protection (face shield) are worn when there is a risk for spills or splashes or when working outside of a C-PEC. Surgical masks are not used when respiratory protection is required per SOP and/or AOR as protection from HD exposure. [USP 800 Section 7.4]	
HD TRAINING & COMPETENCY ASSESSMENT: Personnel who handle HDs are trained and demonstrate competency initially before independently handling HDs, annually, and when a new HD medication, process, SOP, or equipment is introduced. Training minimally includes an overview of the entity's HD list and their risks; review of HD SOPs; proper use of PPE, equipment, and devices; prevention of HD exposures and spills; HD exposure and spill response; use of a spill kit, PPE, and NIOSH-certified respirators; and HD disposal. Based on job duties, personnel receive additional HD training in HD acquisition and receipt, preparation, compounding, dispensing, labeling, storage, and transport. Training and competency assessments are documented. [USP 800 Sections 8, 9, 11.1, 16, & 17]	
HD ATTESTATION: Personnel of reproductive capability have a written acknowledgement attesting to their understanding of HD handling risks. [USP 800 Section 8]	
DEDICATED HD EQUIPMENT: Disposable or cleanable equipment for compounding (e.g., mortar and pestle, graduated cylinder, spatulas) is dedicated for use with HDs. [USP 800 Section 13]	
NON-HD COMPOUNDING IN A C-PEC: Non-HDs compounded in a HD C-PEC are placed in protective outer wrapping, labeled for PPE handling precautions, and treated as an HD. The C-PEC worksurface is decontaminated between compounding of different HDs. [USP 800 Section 5.3.2 and Table 3]	
DEACTIVATION, DECONTAMINATION, CLEANING & DISINFECTION (D/D/C/D): Areas where HDs are handled and all reusable equipment and devices are deactivated/decontaminated, and cleaned. Sterile compounding areas and devices are subsequently disinfected. Written procedures for decontamination, deactivation, cleaning, and disinfection are available and followed. Procedures include agents used, dilutions (if used), frequency, and documentation requirements. Agents selected are appropriate for the type of HD contamination(s), location, and surface materials. Sterile 70% IPA is used to remove residue left on sterile surfaces and compounding areas by decontaminating agents. [USP 800 Section 15]	
D/D/C/D TRAINING & PPE REQUIREMENTS: Personnel are trained in deactivation/decontamination, cleaning, and disinfection to protect themselves and the environment from contamination. Personnel wear appropriate PPE resistant to cleaning agents used, including 2 pairs of ASTM-tested chemotherapy gloves and impermeable disposable gowns. Eye protection and face shields are worn if splashing may occur. [USP 800 Section 15]	
C-PEC D/D/C/D: C-PEC is decontaminated at least daily (when used), after as spill, before and after certification, voluntary interruption, or if ventilation tool is removed. The C-PEC worksurface is decontaminated between compounding of different HDs. The area under the work tray of a C-PEC is deactivated, decontaminated, and cleaned at least monthly. [USP 800 Section 15.2]	
HD LABELING, PACKAGING, TRANSPORT & SPILLS HANDLING: Facility follows SOP for the labeling, handling, packaging, and transport of HDs which addresses the prevention of spills/exposures, training for exposure, and spill handling. HD CSPs are identified as hazardous and labeled with special handling precautions. Labeling process for compounded HD products does not introduce contaminated materials into non-HD areas. [USP 800 Section 11 & 11.2]	
SPILL KITS, & SINGAGE: Spill kits are readily available with appropriate supplies, PPE, and signs to restrict access to affected areas. restriction posted, and documentation of spills occur when needed. [USP 800 Section 16]	

X. LYOPHILIZATION

Sterile preparations prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin. [64B16- 27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. [64B16- 27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	
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. [64B16-27.797(5) F.A.C.]	

Y. SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

Technicians properly identified. [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16- 27.420 F.A.C.].	
Medication is properly labeled for dispensing to patient. [64B16-28.108(2) F.A.C.]	
Outdated medications removed from active stock. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality Related Events are available for inspection. [64B 16 27.300 F.A.C.]; [766.101 (1) (a)(l) F.S.]	
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	
Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] [21CFR1304.04]	
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) F.A.C]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	
A special sterile products and parenteral/enteral compounding pharmacy provides telephone accessibility to its pharmacist(s) for its patients at all hours. [64B16-28.820(3)(b)]	
A special sterile products and parenteral/enteral compounding pharmacy provides special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. [64B16-28.820(3)(b)]	

Z. Miscellaneous

BLOOD-DERIVED OR BIOLOGICAL MATERIAL MANIPULATIONS: 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. [USP 797 Section 1.1.2]	
ALLERGENIC EXTRACTS: Licensed allergenic extracts are mixed and diluted to prepare prescription sets for administration to patients. A prescriptions set is a vial or set or vials of premixed licensed allergenic extracts for subcutaneous immunotherapy that have been diluted with an appropriate diluent for an individual patient. Compounding allergenic extracts 1) minimally complies with all aspects of USP <797> Section 21; 2) involves transfer via sterile needles and syringes of conventionally manufactured sterile allergen products and appropriate conventionally manufactured sterile added substances; and 3) manipulations are limited to penetrating stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile vials. If these conditions are not met, compounding of allergenic extracts follows all aspects of USP <797>. [USP 797 Sections 1.1.2 and 21]	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

Representative:

Date:

Date: