NEVADA STATE BOARD OF PHARMACY

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Sterile Compounding Inspection: Instruction Sheet and Form

(Revised 12/16/2024)

The NVBOP's established self-assessment inspection process provides management the opportunity to review the standards by which the board inspects your operation. The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of pharmaceutical services.

Please have the self-assessment form completed and available for review by the first day of the month listed on your inspection notice. An inspector will review the form with you and inspect your facility during the month listed on your inspection notice.

To minimize any disruption to your facility during the inspection process please have the following available:

1. Completed Sterile Compounding Inspection form along with prior year inspection form.
2. Most recent certification report for ISO classified areas. Documentation of corrective action taken by facility for any failures documented on the certification report.
3. Prior 12 months of aseptic manipulation competency evaluations. Documentation of corrective action taken by facility for any failures.
4. Prior 12 months of competency documentation for personnel.
5. Prior 12 months of garbing competency for compounding personnel.
6. Prior 12 months of Microbiological air and surface monitoring results.
7. Sterility testing data if applicable.
8. Endotoxin testing data if applicable.
9. Examples of Master Formulation Records.
10. Examples of compounding records.
11. Stability data obtained using a stability-indicating analytical method for Category 3 products.
12. Cleaning logs for ISO classified areas.
13. SOP's relevant to the sterile compounding process.

Compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk substance to create a sterile medication.

Specific Practices:

Allergenic Extracts are described in section 21 of the chapter.

When compounding activities require the manipulation of a patient's blood-derived or biological material, the manipulations must be clearly separated from other compounding activities to avoid any cross-contamination.

Repackaging of a sterile product or preparation from its original container into another container must be performed in accordance with the requirements of USP-797.

Compounding of sterile hazardous drugs must additionally comply with USP-800.

Compounding of radiopharmaceuticals is not required to meet the standards of this chapter as they are subject to the requirements of USP-825.

Administration is out of the scope of USP-797.

Compounding of CSPs for direct and immediate administration to a patient is not subject to the requirements for Category 1, Category 2, or Category 3 CSPs when all of the conditions listed in USP-797 are met.

Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer.

Docking and activation of proprietary bag and vial systems in accordance with the manufacturer's labeling for immediate administration to an individual patient is not considered compounding and may be performed outside an ISO 5 environment.

Docking of the proprietary bag and vial systems for future activation and administration is considered compounding and must be performed in accordance with USP-797.

Beyond Use Dates for proprietary bag and vial systems must not be longer than those specified in the manufacturer's labeling.

Pharmacy Information	
Date Completed:	
Pharmacy Name:	
Pharmacy License #:	
Pharmacy Address:	
Pharmacy Telephone #:	
Pharmacy Fax #:	
Pharmacy Email:	
Managing Pharmacist Name:	
Managing Pharmacist start date:	
Name of Designated person(s):	

List of compounding personnel approved to compound sterile products (Make copies of this page if additional space is needed)				
#	Name (First, Last)	License Number	Position	Category Qualified to Compound
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

General Information				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 1.5	Pharmacy compounds Category 1 compounded sterile products?			
USP 797 Section 1.5	Pharmacy compounds Category 2 compounded sterile products?			
USP 797 Section 1.5	Pharmacy compounds Category 3 compounded sterile products?			

Personnel Training and Evaluation Documentation				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 2	Documentation is on file for each person who compounds sterile products or personnel who have direct oversight of compounding personnel that the person is competent and proficient to correctly perform all tasks related to sterile compounding and has received initial and ongoing training to establish and maintain their competency?			
The following records for personnel are completed on an initial and every 12 month basis: General requirements				
USP 797 Section 2.1	Hand hygiene?			
	Garbing?			
	Cleaning and disinfection?			
	Calculations, measuring, and mixing?			
	Aseptic technique?			
	Achieving and/or maintaining sterility and apyrogenecity?			
	Use of equipment?			
	Documentation of the compounding process?			
	Principles of HEPA filtered unidirectional airflow within the ISO-5 environment?			
	Proper use of primary engineering controls?			
	Principles of movement of materials and personnel within the compounding area?			
The following records for personnel are completed on an initial basis and then at an interval listed below: Garbing and GFT testing				
USP 797 Section 2.2	Successfully complete initial garbing competency evaluation of no fewer than 3 separate times? (successful completion for initial test is defined as zero cfu's for both hands)			
USP 797 Section 2.2	Successfully complete ongoing garbing at least once every 6 months for personnel compounding Category 1 and Category 2 CSPs, and at least once every 3 months for personnel compounding Category 3 CSPs? (every 12 months for personnel who have direct oversight of compounding personnel) (successful completion for ongoing test is defined as <= 3cfu's for both hands)			
USP 797 Section 2.3	If conducting gloved fingertip and thumb sampling in a CAI or CACI the samples are taken from the sterile gloves placed over the gloves attached to the unit?			
USP 797 Section 2.2	Documentation of failure and re-testing is maintained?			
The following records for personnel are completed on an initial basis and then at an interval listed below: Media fill testing				
USP 797 Section 2.3	Successfully complete an initial aseptic manipulation evaluation which consists of a visual observation, media fill testing, gloved fingertip sampling listed in Section 2.2, and surface sampling of the direct compounding area?			
	Successfully complete an ongoing aseptic manipulation evaluation which consists of a visual observation, media fill testing, gloved fingertip sampling listed in Section 2.2, and surface sampling of the direct compounding area. Completed every 6 months for personnel compounding Category 1 and Category 2 CSPs and every 3 months for personnel compounding Category 3 CSPs. Completed every 12 months for personnel who have direct oversight of compounding personnel?			
	The media-fill test simulates the most difficult and challenging aseptic compounding procedures encountered by the compounding person?			
USP 797 Section 2.3	Documentation of failure and re-testing is maintained?			

Personal Hygiene and Garbing				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 3	Individuals that may have a higher risk of contaminating the CSP and the environment report these conditions to the designated person?			
Personnel Preparation				
USP 797 Section 3.1	There is no food or drinks in the anteroom, buffer room, or segregated compounding areas?			
USP 797 Section 3.1	Before entering a compounding area all personnel remove outer garments, remove all cosmetics, remove any exposed jewelry, don't wear headphones or earbuds, don't bring electronic devices that are not necessary for compounding into the area, keep nails clean and neatly trimmed, don't wear nail products, and wipe eyeglasses if worn?			
USP 797 Section 3.1	The designated person documents any accommodations made for personnel?			
Hand Hygiene				
USP 797 Section 3.2	Personnel wash hands and forearms up to the elbows with soap and water before initiating compounding activities?			
USP 797 Section 3.2	Brushes are not used for hand hygiene?			
USP 797 Section 3.2	Hand dryers are not used for hand hygiene?			
USP 797 Section 3.2	A closed system of soap is readily available?			
USP 797 Section 3.2	Debris is removed from underneath fingernails using a disposable nail cleaner?			
USP 797 Section 3.2	Hands and forearms are washed for at least 30 seconds?			
USP 797 Section 3.2	Hands and forearms are dried with low-lint disposable towels?			
USP 797 Section 3.2	Hands are sanitized with an alcohol-based hand rub prior to donning sterile gloves?			
USP 797 Section 3.2	Sterile gloves are donned in a classified room or SCA?			
Garbing Requirements				
USP 797 Section 3.3	The order of garbing is documented in the facility's SOP's?			
USP 797 Section 3.3	If hand hygiene is completed outside of a classified area, alcohol-based hand rub is used prior to donning garb?			
USP 797 Section 3.3	Skin is not exposed inside the ISO Class 5 PEC?			
USP 797 Section 3.3	The following minimum requirements for preparing Category 1 and Category 2 CSPs are met by the organization? Low-lint garment with sleeves that fits snugly around the wrists and is enclosed at the neck, low-lint covers for shoes, low-lint cover for head that covers the hair and ears, low-lint face mask, sterile powder-free gloves.			
USP 797 Section 3.3	When compounding within a CAI or CACI sterile gloves are worn over gloves attached to the RABS sleeve?			
USP 797 Section 3.3	The only garb that is reused are gowns and only if compounding Category 1 and Category 2 CSPs? The gown may be reused within the same shift by the same person if the gown is maintained in a classified area or adjacent to, or within, the SCA in a manner that prevents contamination.			
USP 797 Section 3.3	When compounding Category 3 CSPs the following additional garbing requirements are met in the buffer room? No exposed skin in the buffer room, all low-lint outer garb must be sterile, including the use of sterile sleeves when a CAI or CACI is used.			

Facilities and Engineering Controls				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 4 – 4.1.2	The anteroom providing access to positive pressure buffer room meets at least ISO 8 classification?			
USP 797 Section 4 – 4.1.2	The anteroom providing access to negative pressure buffer room meets at least ISO 7 classification?			
USP 797 Section 4 – 4.1.2	Buffer room meets at least ISO 7 classification?			
USP 797 Section 4 – 4.1.2	Category 1, Category 2, and Category 3 CSPs are prepared in an ISO Class 5 or better PEC?			
USP 797 Section 4 – 4.1.2	Pharmacy only compounds Category 1 CSPs and the PEC is placed in an unclassified area?			
Facility Design and Environmental Controls				
USP 797 Section 4.2	The temperature and humidity are monitored and documented at least once daily or through continuous monitoring systems?			
USP 797 Section 4.2	Free standing humidifiers/dehumidifiers and air conditioners are not used within the classified areas or within the perimeter of the SCA?			
Types of SECs and Design				
USP 797 Section 4.2.1	Access to the SEC is restricted to authorized personnel and required materials?			
USP 797 Section 4.2.1	The following are required for Cleanroom suites:			
USP 797 Section 4.2.1	Air supplied to the cleanroom suite is introduced through HEPA filters that are located in the ceiling of the buffer and anterooms?			
USP 797 Section 4.2.1	Air returns in the cleanroom suite are low on the wall?			
USP 797 Section 4.2.1	The classified rooms are equipped with a pressure differential monitoring system?			
USP 797 Section 4.2.1	If a pass-through is used both doors are never opened at the same time?			
USP 797 Section 4.2.1	Tacky mats are not placed within ISO-classified areas?			
USP 797 Section 4.2.1	The following are required for Segregated Compounding Areas:			
USP 797 Section 4.2.1	Only Category 1 CSPs are compounded in an SCA?			
USP 797 Section 4.2.1	The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow?			
USP 797 Section 4.2.1	The SCA is not located in a restroom, warehouse, or food preparation area?			
The CSP Compounding Environment				
USP 797 Section 4.2.2	The PEC is certified to meet ISO Class 5 or better conditions during dynamic operating conditions?			
USP 797 Section 4.2.2	Unidirectional airflow is maintained in the PEC?			
USP 797 Section 4.2.2	HEPA-filtered air is supplied by the PEC at a velocity sufficient to sweep away particles from critical sites and maintain unidirectional airflow during operations?			
Types of PECs and Placement				
USP 797 Section 4.2.3	Placement of the PEC allows for cleaning around the PEC?			
USP 797 Section 4.2.3	PEC is placed in an ISO Class 7 positive pressure buffer room with an ISO Class 8 positive pressure anteroom for non-hazardous compounding of Category 2 and Category 3 CSPs?			
USP 797 Section 4.2.3	A dynamic airflow smoke pattern test is performed in the PEC initially and at least every 6 months thereafter?			
USP 797 Section 4.2.3	Laminar Airflow Workbench (LAFW):			
USP 797 Section 4.2.3	LAFW is not used in the preparation of antineoplastics and/or API HDs?			
USP 797 Section 4.2.3	LAFW provides either horizontal or vertical unidirectional HEPA-filtered airflow?			
USP 797 Section 4.2.3	Integrated vertical laminar flow zone (IVLFZ):			
USP 797 Section 4.2.3	IVLFZ is a designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room? The unidirectional HEPA-filtered zone is separated from the ISO Class 7 area with a physical barrier?			

USP 797 Section 4.2.3	Both static and dynamic smoke studies are documented?			
USP 797 Section 4.2.3	Class 2 biological safety cabinet (BSC):			
USP 797 Section 4.2.3	The exhaust air from the BSC is externally vented for preparation of antineoplastic and/or API HDs?			
USP 797 Section 4.2.3	Restricted Access Barrier System (RABS): Examples include CAI and CACI			
USP 797 Section 4.2.3	The recovery time after opening the transfer chamber to achieve ISO Class 5 air quality is documented?			
Air Exchange Requirements				
USP 797 Section 4.2.4	ISO Class 7 room requirements:			
USP 797 Section 4.2.4	A minimum of 30 total HEPA filtered ACPH is supplied to ISO Class 7 rooms?			
USP 797 Section 4.2.4	At least 15 ACPH of the total air exchange in a room comes from the HVAC through HEPA filters located in the ceiling?			
USP 797 Section 4.2.4	The HEPA-filtered air from the PEC, when added to the HVAC-supplied HEPA-filtered air, increases the total HEPA-filtered ACPH to at least 30 ACPH?			
USP 797 Section 4.2.4	If the PEC is used to meet the minimum total ACPH requirement then the PEC is not turned off except for maintenance?			
USP 797 Section 4.2.4	The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH is documented on the certification report?			
USP 797 Section 4.2.4	ISO Class 8 room requirements:			
USP 797 Section 4.2.4	A minimum of 20 total HEPA filtered ACPH is supplied to ISO Class 8 rooms?			
USP 797 Section 4.2.4	At least 15 ACPH of the total air exchange in a room comes from the HVAC through HEPA filters located in the ceiling?			
USP 797 Section 4.2.4	The total ACPH is documented on the certification report?			
Establishing and Maintaining Pressure Differentials				
USP 797 Section 4.2.5	Continuous differential positive pressure monitoring is performed?			
USP 797 Section 4.2.5	In the clean-room suite a minimum differential positive pressure of 0.020-inch water column is maintained between each classified area?			
USP 797 Section 4.2.5	FYI – No pressure differential is required between the SCA and the surrounding area			
USP 797 Section 4.2.5	The quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding occurs?			
Facilities preparing Category 2 or Category 3 CSPs from non-sterile starting components must meet the following requirements				
USP 797 Section 4.2.6	Pre-sterilization procedures such as weighing and mixing are completed in an ISO Class 8 or better environment?			
USP 797 Section 4.2.6	CVE, BSC, or CACI used for pre-sterilization is certified at least every 6 months?			
USP 797 Section 4.2.6	Personnel are following the hygiene and garbing requirements during the pre-sterilization procedures?			
Creating Areas to Achieve Easily Cleanable Conditions				
USP 797 Section 4.3.1	Cleanroom Suite requirements:			
USP 797 Section 4.3.1	Surfaces are smooth, impervious, free from cracks and crevices, and non-shedding?			
USP 797 Section 4.3.1	Junctions are sealed?			
USP 797 Section 4.3.1	If ceilings contain inlaid panels, the panels are caulked around each panel to seal them to the support frame?			
USP 797 Section 4.3.1	Walls are constructed of or covered with durable material?			
USP 797 Section 4.3.1	Panels are joined together and sealed to each other and the support structure?			
USP 797 Section 4.3.1	Floors include coving to the sidewall or the junction between the floor and the wall are caulked?			
USP 797 Section 4.3.1	The exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed?			
USP 797 Section 4.3.1	All other penetrations through the ceiling or walls are sealed?			

USP 797 Section 4.3.1	SCA requirements:			
USP 797 Section 4.3.1	All surfaces are clean, uncluttered, and dedicated to compounding?			
Water Sources				
USP 797 Section 4.4	Surfaces of sink are cleaned and disinfected each day of use and a sporicidal agent is applied at least monthly?			
USP 797 Section 4.4	If the sink is located outside of the anteroom then it is located in a clean space?			
USP 797 Section 4.4	The buffer room doesn't contain any plumbed water sources?			
USP 797 Section 4.4	The anteroom doesn't contain any floor drains?			
USP 797 Section 4.4	If utilizing a SCA design, the sink is placed at least 1 meter away from the PEC?			
Placement and Movement of Materials				
USP 797 Section 4.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the classified areas or SCA?			
USP 797 Section 4.5	There are no shipping cartons or other corrugated or uncoated cardboard allowed in the classified areas or SCA?			
USP 797 Section 4.5	Carts used to transport into classified areas are constructed from nonporous materials with cleanable casters and wheels?			
USP 797 Section 4.5	In the clean-room suite the carts are not moved from the dirty side to the clean side of the anteroom unless the entire cart, including the casters, are cleaned and disinfected?			
USP 797 Section 4.5	Proper placement of equipment in a PEC is initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow?			
USP 797 Section 4.5	The dynamic airflow smoke pattern test is repeated if equipment is placed in a different location?			
USP 797 Section 4.5	Any items removed from the classified areas or SCA are disinfected before they are returned to the classified areas or the SCA?			
USP 797 Section 4.5	Materials necessary for performing compounding activities that have been exposed in patient care and treatment areas are not allowed to enter anterooms, buffer rooms, or SCA unless they have been thoroughly cleaned and disinfected?			

Certification and Recertification				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 5	Independent certification of the classified areas including the PEC are performed initially and recertification is performed at least every 6 months?			
USP 797 Section 5	Certification includes airflow testing, HEPA filter integrity testing, total particle count testing, dynamic airflow smoke pattern testing, number of personnel present in each PEC and SEC during total particle count tests and dynamic airflow smoke pattern tests documented?			
USP 797 Section 5	Classified areas are recertified if there are changes to the area such as redesign, construction, replacement, or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality?			
USP 797 Section 5	All certification and recertification reports are reviewed by the designated person?			
USP 797 Section 5	A corrective action plan is implemented and documented in response to any out-of-range result?			
USP 797 Section 5	Data collected in response to corrective actions are reviewed to confirm that the actions taken have been effective?			
Total Airborne Particle Sampling				
USP 797 Section 5.1	Total airborne particle count testing is conducted in all classified areas during dynamic operating conditions at least every 6 months?			
USP 797 Section 5.1	Total airborne particle sampling sites are selected in all classified areas?			

USP 797 Section 5.1	If levels measured during the total air sampling program exceed the criteria for the ISO classification of the areas sampled, a cause is investigated and corrective action taken and documented?			

Microbiological Air and Surface Monitoring				
Citation	**Question**	**Yes**	**No**	**NA**
UPS 797 Section 6	A written procedure for microbiological air and surface monitoring has been developed and implemented?			
UPS 797 Section 6	All microbiological air and surface monitoring procedures, the test results, and the corrective actions are documented?			
UPS 797 Section 6	Data collected in response to corrective actions have been reviewed to confirm that the actions taken have been effective?			
General Monitoring Requirements				
USP 797 Section 6.1	The microbiological air and surface monitoring program includes both viable impact volumetric particulate sampling and surface sampling?			
USP 797 Section 6.1	Regular review of the sampling data is performed to detect trends and the results of the review are documented?			
USP 797 Section 6.1	Microbiological air and surface monitoring is performed initially and then monitored according to the minimum frequencies outlined in USP 797?			
USP 797 Section 6.1	Microbiological air and surface monitoring is conducted in all classified areas during dynamic operating conditions?			
USP 797 Section 6.1	Sampling is performed in the following circumstance: In conjunction with the certification of new facilities or equipment, after any servicing of facilities or equipment, in response to identified problems, in response to identified trends, or in response to changes that could impact the sterile compounding environment?			
USP 797 Section 6.1	Surface sampling is performed at the end of a compounding activity or shift, but before the area has been cleaned and disinfected?			
USP 797 Section 6.1	All active air sampling devices are serviced and calibrated as recommended by the manufacturer?			
Monitoring Air Quality For Viable Airborne Particles				
USP 797 Section 6.2	A monitoring program for viable airborne particles has been developed and implemented to assess microbiological air quality in all classified areas?			
USP 797 Section 6.2.1	Volumetric active air sampling is conducted in all classified areas using an impaction device during dynamic conditions?			
USP 797 Section 6.2.1	This test is performed at least every 6 months for locations compounding Category 1 and Category 2 CSPs?			
USP 797 Section 6.2.1	This test 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?			
USP 797 Section 6.2.1	Air sampling sites are selected in all classified areas.			
USP 797 Section 6.2.2	A general microbiological growth media that supports the growth of bacteria and fungi is used?			
USP 797 Section 6.2.2	Samples are incubated in an incubator at the temperatures listed in USP 797?			
USP 797 Section 6.2.2	The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and the results are reviewed and documented?			
USP 797 Section 6.2.2	The incubator is placed in a location outside the sterile compounding area?			
USP 797 Section 6.2.3	If levels exceed the action levels described in USP 797 the cause is investigated and corrective action taken?			
USP 797 Section 6.2.3	If levels exceed the action levels described in USP 797 then at attempt is made to identify any microorganisms recovered to the genus level?			
USP 797 Section 6.2.3	If levels exceed the action levels the corrective action plan is documented and includes resampling of failed areas to confirm corrective action was successful?			

Monitoring Surfaces for Viable Particles				
USP 797 Section 6.3.1	Surface sampling is performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected?			
USP 797 Section 6.3.1	If compounding Category 1 and Category 2 CSPs the surface sampling of all classified areas and pass-through chambers connecting to classified areas are conducted at least monthly?			
USP 797 Section 6.3.1	If compounding Category 3 CSPs, a surface sampling is performed of all classified areas and pass-through chambers connecting to classified areas is completed prior to assigning a BUD longer than the limits established in USP 797 and at least weekly on a regular scheduled basis regardless of the frequency of compounding Category 3 CSPs?			
USP 797 Section 6.3.1	Surface sampling is conducted within the PEC used to prepare Category 3 CSPs at the end of each batch before cleaning and disinfection occurs?			
USP 797 Section 6.3.2	Surface sampling media devices contain microbiological growth media for sampling flat surfaces are utilized?			
USP 797 Section 6.3.2	After sampling the sampled area is cleaned and disinfected?			
USP 797 Section 6.3.2	Samples are incubated in an incubator at the temperatures listed in USP 797?			
USP 797 Section 6.3.2	If levels exceed the action levels described in USP 797 the cause is investigated and corrective action taken?			
USP 797 Section 6.3.2	If levels exceed the action levels the corrective action plan is documented and includes resampling of failed areas to confirm corrective action was successful?			

Cleaning, Disinfection, and Applying Sporicidal Disinfectants and Sterile 70% IPA				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 7	Surfaces are cleaned prior to being disinfected unless an EPA registered one-step disinfectant cleaner is used to accomplish both the cleaning and disinfecting?			
USP 797 Section 7	Sporicidal agents are used monthly for entities compounding Category 1 and/or Category 2 CSPs?			
USP 797 Section 7	Sporicidal agents are used weekly for entities compounding Category 3 CSPs?			
USP 797 Section 7	In a PEC, sterile 70% IPA is applied after cleaning and disinfecting, or after the application of a one-step disinfectant cleaner or sporicidal disinfectant, to remove any residue?			
USP 797 Section 7	Sterile 70% IPA is applied immediately before initiating compounding?			
USP 797 Section 7	During compounding sterile 70% IPA is applied to the horizontal work surface of the PEC at least every 30 minutes?			
USP 797 Section 7	Cleaning is performed in the direction of clean to dirty areas?			
USP 797 Section 7	The pharmacy has SOP's related to their cleaning procedures?			
USP 797 Section 7.1.1	All products used are allowed to dwell for the minimum contact time specified by the manufacturer?			
USP 797 Section 7.1.1	Cleaning, disinfecting, and sporicidal agents used within the PEC are sterile?			
USP 797 Section 7.1.1	If diluting cleaning products the water used is sterile?			
USP 797 Section 7.1.2	All cleaning and disinfecting supplies are low lint?			
USP 797 Section 7.1.2	Cleaning and disinfecting supplies used in the PEC are sterile?			
USP 797 Section 7.1.2	Disposable supplies are discarded after each cleaning activity?			
USP 797 Section 7.1.2	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal?			

Introducing Items Into the SEC and PEC				
Citation	**Question**	**Yes**	**No**	**NA**
Introducing Items Into the SEC				
USP 797 Section 8.1	Before any item is introduced into the clean side of the anteroom, placed into pass-through, or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA registered disinfectant, or sterile 70% IPS using low lint wipers by personnel wearing gloves?			
Introducing Items Into the PEC				
USP 797 Section 8.2	Just before any item is introduced into the PEC it is wiped with sterile 70% IPA and allowed to dry before use?			
Use of Sterile 70% IPA on Critical Sites within the PEC				
USP 797 Section 8.3	Critical sites are wiped with sterile 70% IPA in the PEC and allowed to dry before personnel enter or puncture stoppers and septums or break the necks of ampules?			

Equipment, Supplies, and Components				
Citation	**Question**	**Yes**	**No**	**NA**
Equipment				
USP 797 Section 9.1	Equipment brought into the classified areas are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low lint wipers?			
USP 797 Section 9.1	Before using automated compounding devices or other similar equipment, the compounding personnel conduct an accuracy assessment before the first use and again each day the equipment is used?			
USP 797 Section 9.1	The daily record of the accuracy measurements are maintained?			
Supplies				
USP 797 Section 9.2	Supplies in direct contact with the CSP are sterile and depyrogenated?			
Component Selection				
USP 797 Section 9.3.1	APIs comply with the criteria in the USP-NF monograph, if one exists, have a COA, and are obtained from an FDA-registered facility?			
Component Receipt				
USP 797 Section 9.3.2	The date of receipt by the compounding facility is clearly marked on each API or added substance package that lacks a vendor expiration date?			
	Packages of components that lack a vendor's expiration date are assigned a conservative expiration date, not to exceed 1 year after receipt by the compounding facility?			
Component Evaluation Before Use				
USP 797 Section 9.3.3	Compounding personnel ascertain before use that components for CSPs are of the correct identity, appropriate quality, within expiry date, and have been stored under appropriate conditions?			
USP 797 Section 9.3.4	All components are handled and stored in a manner that prevents contamination, mix-up's, and deterioration?			
USP 797 Section 9.3.4	Personnel monitor temperature in the area where components are stored at least once daily on days that the facility is open and the readings are documented or readily available from a continuous monitoring device?			

Sterilization and Depyrogenation				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 10	Pharmacy follows all required guidelines listed in USP 797 for depyrogenation?			
USP 797 Section 10	Pharmacy follows all required guidelines listed in USP 797 for sterilization by filtration?			

USP 797 Section 10	Pharmacy follows all required guidelines listed in USP 797 for sterilization by steam heat?			
USP 797 Section 10	Pharmacy follows all required guidelines listed in USP 797 for sterilization by dry heat?			

Master Formulations and Compounding Records				
Citation	**Question**	**Yes**	**No**	**NA**
Creating Master Formulation Records				
USP 797 Section 11.1	A master formulation record is created for CSPs prepared for more than 1 patient and for CSPs prepared from nonsterile ingredients?			
USP 797 Section 11.1	The master formulation record is a detailed record of procedures that describes how the CSP is to be prepared?			
USP 797 Section 11.1	Any changes or alterations to the MFR are approved and documented according to the facility's SOPs?			
USP 797 Section 11.1	The pharmacy is following all of the requirements for MFR's outlined in USP 797?			
Creating Compounding Records				
USP 797 Section 11.2	A compounding record is created for all CSPs for Category 1, Category 2, and Category 3. A CR is also created for immediate use CSPS's prepared for more than one patient?			
USP 797 Section 11.2	The compounding record is stored electronically?			
USP 797 Section 11.2	The pharmacy is following all of the requirements for CR's outlined in USP 797?			

Release Inspection and Testing				
Citation	**Question**	**Yes**	**No**	**NA**
Visual Inspection				
USP 797 Section 12.1	At the completion of compounding, before release and dispensing, the CSP is visually inspected to determine whether the physical appearance of the CSP is as expected?			
USP 797 Section 12.1	The CSP is visually inspected to confirm that the CSP and its labeling match the prescription or medication order?			
USP 797 Section 12.1	The CSP is visually inspected for container-closure integrity?			
Sterility Testing				
USP 797 Section 12.2	FYI – Sterility testing is not required for Category 1 CSPs			
USP 797 Section 12.2	If a Category 2 CSP is assigned a BUD that requires sterility testing and all Category 3 CSPs, the testing is performed according to USP 71 or a validated alternative method?			
USP 797 Section 12.2	The pharmacy is following all of the requirements for sterility testing outlined is USP 797?			
Bacterial Endotoxin Testing				
USP 797 Section 12.3	FYI – Category 1 injectable CSPs do not require testing for bacterial endotoxin			
USP 797 Section 12.3	Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility and Category 3 injectable CSPs compounded from one or more nonsterile component(s) are tested to ensure that they do not contain excessive bacterial endotoxins?			

Labeling				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 13	The pharmacy is following all of the labeling requirements as outlined is USP 797?			
USP 797 Section 13	If the CSP is sent outside the facility in which it was compounded the label includes the contact information of the compounding facility?			

Establishing Beyond-Use Dates				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 14.1	Each CSP states the date, or the hour and date, beyond which the preparation must not be used and must be discarded?			
USP 797 Section 14.2.4	Once a CSP is thawed from a frozen state, the CSP is not refrozen?			
USP 797 Section 14.3	The BUD does not exceed the shortest remaining expiration date of any of the commercially available starting components?			
USP 797 Sections 14.3	Pharmacy is following USP 797 BUD guidelines for Category 1 CSPs?			
USP 797 Sections 14.3	Pharmacy is following USP 797 BUD guidelines for Category 2 CSPs?			
USP 797 Sections 14.3	Pharmacy is performing sterility testing on Category 2 CSPs in order to extend BUDs?			
USP 797 Sections 14.3	Pharmacy is performing terminal sterilization on Category 2 CSPs?			
USP 797 Sections 14.3	Pharmacy is following USP 797 BUD guidelines for Category 3 CSPs?			
USP 797 Sections 14.3	Pharmacy is performing terminal sterilization on Category 3 CSPs?			
USP 797 Sections 14.4.1	Category 3 CSPs are not assigned a BUD longer than the limits established by USP 797?			
USP 797 Sections 14.4.3	The BUD assigned to a Category 3 CSP is supported by stability data obtained using a stability-indicating analytical method?			
USP 797 Sections 14.4.3	The Category 3 CSP is prepared according to the exact formulation from which the stability data is derived?			
USP 797 Sections 14.4.3	The Category 3 CSP is packaged and stored in a container closure of the same materials of composition as that used in the study?			
USP 797 Sections 14.4.3	If the Category 3 CSP is an injection or if it is an ophthalmic solution a particulate matter test is conducted once per formulation with acceptable results?			

Multiple Dose CSPs				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 14.5	Multiple dose CSPs are prepared as a Category 2 or Category 3 CSP?			
USP 797 Section 14.5	An aqueous multiple dose CSP has passed antimicrobial effectiveness testing in accordance with USP Chapter 51?			
USP 797 Section 14.5	After a multiple dose container is initially entered or punctured, the multiple dose container is not used for longer than the assigned BUD or 28 days, whichever is shorter?			

Use of Conventionally Manufactured Products as Components				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 15.1	If a single dose vial is entered or punctured only in an ISO Class 5 or cleaner air, it is only used up to 12 hours after initial entry or puncture as long as the storage requirements during that 12 hour period are maintained?			

USP 797 Section 15.1	Opened single dose ampules are not stored for any time period?			

Use of CSPs as Components				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 16	The component CSP is assigned a BUD consistent with USP 797 and is stored under conditions for its assigned BUD when not in use?			
USP 797 Section 16	The final CSP is assigned a BUD consistent with USP 797?			
USP 797 Section 16.1	Multiple dose CSPs are stored under the conditions upon which its BUD is based?			
USP 797 Section 16.2	When a compounded single dose CSP or CSP stock solution is used as a component to compound additional CSPs, the original single dose 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?			
USP 797 Section 16.2	The component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter?			

SOPs				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 17	SOPs have been developed for CSPs and a designated person has ensured that they are appropriate and implemented?			
USP 797 Section 17	SOPS are reviewed initially and at least every 12 months by the designated person?			

Quality Assurance and Quality Control				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 18	The designated person has ensured that the facility has a formal, written QA and QC program?			
USP 797 Section 18	The overall QA and QC program is reviewed at least once every 12 months by the designated person?			
USP 797 Section 18.1	The designated person has created a documented recall process?			
USP 797 Section 18.2	The facility has developed and implemented SOPs for handling complaints?			
USP 797 Section 18.2	The designated person reviews all complaints?			
USP 797 Section 18.2	A readily retrievable written or electronic record of each complaint is kept by the facility?			
USP 797 Section 18.2	A record is kept including the findings of any investigation and any follow-up?			
USP 797 Section 18.3	Adverse events potentially associated with the quality of CSPs are reported in accordance with the facility's SOPs?			

CSP Handling, Storage, Packaging, Shipping, and Transport				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 19.1	A controlled temperature area is established and monitored to ensure that the temperature remains within the appropriate range for the CSP?			
USP 797 Section 19.2	If the CSP is sensitive to light, light-resistant packaging material is used?			

Documentation				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 20	The compounding facility maintains written or electronic documentation to demonstrate compliance with the requirements of USP 797?			

Notes

Your location will be inspected by an agent of the Nevada Board of Pharmacy. **All unsatisfactory conditions must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business. Please attach a copy of any documentation and corrective action you have taken to this inspection form for future review on inspection.**

Date:	
Pharmacist Printed Name:	
Pharmacist Signature:	