Kentucky Board of Pharmacy
125 Holmes St.
Frankfort, KY 40601

Report

Pharmacy

Name: *Demo Pharmacy* **Permit No.**: *P0DEMO*

Address: *State Off. Bldg.Annex Ste 300, Frankfort, KY 40601*

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Inspection

Date: *06/10/2019* **Time In**: *7:47 AM* **Time Out**:

Type: *Initial*

Notes: *None*

Pharmacist and Interns

Policies and Procedures

Compounding Personnel Education and Assessment	*Compliant*
Personnel Cleansing and Garbing	*Compliant*
Cleaning and Disinfecting Compounding Area	*Compliant*
Operation of Isolators	*Compliant*
Compounding Procedures for In-Process Checks and Final Product Verification	*Compliant*
Ingredient Inspection and Assessment	*Compliant*
Checks for Compounding Accuracy and Recordkeeping of Compounding Log	*Compliant*
Physical Inspection of CSPs	*Compliant*
Final Check of CSPs Including Labeling	*Compliant*
Maintenance and Assessment of Compounding Equipment	*Compliant*
Assignment of BUDs	*Compliant*
Monitoring of Storage Areas	*Compliant*
Packaging, Handling, Security, Storage, Disposal, Destruction, Transport and Return of CSPs and Supplies	*Compliant*
Quality Assurance Program	*Compliant*

Policies and Procedures *(continued)*

Adverse Events Reporting and Monitoring	*Compliant*
Hazardous and Oncology Drug Handling and Disposal	*Compliant*
Sterilization by Steam	*Compliant*
Sterilization by Dry Heat	*Compliant*
Depyrogenation by Dry Heat	*Compliant*
Monitoring of CSPs Dispensed Prior to Sterility Results, including Recall Procedures	*Compliant*
P&P reviewed and revised annually	*Compliant*

Training and Garbing

Documentation all compounding personnel passed initial and annual/semi-annual written exam for appropriate risk level for cleaning and disinfecting.	*Compliant*
Documentation all compounding personnel passed initial and annual/semi-annual written exam for hand hygiene and garbing.	*Compliant*
Documentation all compounding personnel passed initial and annual/semi-annual written exam for aseptic technique.	*Compliant*
Visually observed and appropriately documented competencies of cleaning and disinfecting, initially and at the completion of media fill test, and including environmental services, if applicable and when appropriate.	*Compliant*
Visually observed and appropriately documented competencies of hand hygiene and garbing, initially with initial gloved fingertip sample with zero growth.	*Compliant*
Visually observed and appropriately documented competencies of hand hygiene and garbing annually/semi-annually done upon completion of aseptic media fill test performed annually/semi-annually with up to 3 total CFUs.	*Compliant*
Visually observed and appropriately documented competencies of aseptic technique, initially and annually/semi-annually for appropriate risk level under most challenging conditions.	*Compliant*
Training of any equipment used.	*Compliant*
Documentation of immediate reinstruction, reevaluation and retesting of compounding personnel who fail any testing.	*Compliant*
Written policy personnel cannot compound if have sunburn, illness, open sores, etc.	*Compliant*
Personnel remove outer garments, make-up, visible jewelry (hand, wrist, ears, lips, eyebrow piercings).	*Compliant*

Training and Garbing *(continued)*

Personnel keep nails short and natural.	*Compliant*

Garbing

Garb from dirtiest to cleanest, using the line of demarcation appropriately.	*Compliant*
Performs hand washing appropriately up to the elbows for 30 seconds and uses a nail pick.	*Compliant*
Use waterless, alcohol based surgical scrub with persistent activity. Has chlorhexidine/emollients: Purell Surgical Scrug; Avagard; Sterillium; Surgicept; Triseptin; Alcare.	*Compliant*
Sterile gloves donned appropriately.	*Compliant*
Dispose of gown when leave compounding area or reuse for one shift (nonhazardous).	*Compliant*
Non-garbed personnel are not entering compounding area.	*Compliant*

Environment with Ante and Buffer Rooms

Floor is smooth, impervious, free from cracks and crevices, and seams are heat sealed.	*Compliant*
Ceiling tiles are sealed, free from cracks and crevices, and seams where walls and ceiling meet are sealed.	*Compliant*
Walls are painted with epoxy based paint or other impermeable surface, are smooth, impervious, easily cleanable, and free from cracks and crevices, seams are heat sealed.	*Compliant*
Non-shedding equipment is used.	*Compliant*
Limited entry to necessary personnel.	*Compliant*
Accessories: shelving, chairs, stools, carts easily cleanable and non-permeable, free from cracks and crevices, low particulate generating and limited to necessary equipment in ante and buffer rooms.	*Compliant*
All items cleaned and disinfected before bringing into buffer room.	*Compliant*
Ante Room has a sink with hot and cold water and hands dried with lint free non-shedding, disposable paper towels or blow dryer.	*Compliant*
Buffer Room has no sink, drain or water source.	*Compliant*
Proper utilization of line of demarcation (LOD).	*Compliant*
HEPA Filters must be on air ducts in the ceiling of ante and buffer rooms.	*Compliant*
Food, drinks, gum prohibited in compounding area.	*Compliant*

Environment with Ante and Buffer Rooms *(continued)*

If LAFW Blower turned off, must run for 30 minutes before using.	*Compliant*
If no physical barrier between the buffer and ante rooms, only performing low and medium risk sterile compounding.	*Compliant*
If no physical barrier between the buffer and ante rooms, air velocity is at least 40 feet/minute continuously from buffer area across LOD into ante area.	*Compliant*
If no physical barrier between the buffer and ante rooms, air velocity is recorded every shift, a minimum of daily.	*Compliant*
Pressure is recorded each shift, a minimum of daily.	*Compliant*
Ante room is positive pressure of at least 0.02 inch water column to general pharmacy.	*Compliant*
Buffer room is positive pressure of at least 0.02 inch water column to ante room.	*Compliant*
Temperature is recorded daily.	*Compliant*
Temperature of buffer room is appropriate.	*Compliant*
Controlled storage areas for room temperature is 68 to 77 F or 20 to 25 C.	*Compliant*
Controlled storage area for cold temperature is 36 to 46 F or 2 to 8 C.	*Compliant*
Controlled storage area for freezer temperature is -13 to 14 F or -25 to -10 C.	*Compliant*
Components store in appropriate humidity, recommended 35% to 60%.	*Compliant*

Cleaning

Personnel appropriately garbed when cleaning.	*Compliant*
Cleaning and disinfecting agent (may be one step cleaning and disinfecting) appropriate for bacteria, viruses, fungi.	*Compliant*
Cleaning equipment is non-shedding, disposable or dedicated.	*Compliant*
Daily cleaning of compound area takes place when no compounding is occurring and includes easily cleanable surfaces including counter tops, pass through, etc. and floors.	*Compliant*
Monthly cleaning of compound area takes place when no compounding is occurring and includes everything in compound area – bins, equipment, ceiling, walls and floor.	*Compliant*
Cleaning of ISO Class 5 PEC is documented each shift, a minimum of daily.	*Compliant*
Uses low linting towels to clean ISO Class 5 PEC.	*Compliant*

Cleaning *(continued)*

Uses germicidal detergent diluted with sterile water if not ready to use, to clean each shift or daily.	*Compliant*
ISO Class 5 PEC is disinfected between compounding activities.	*Compliant*
ISO Class 5 PEC is wiped with sterile water followed by disinfectant after spills or surface contamination.	*Compliant*
70% sIPA allowed to remain in contact with surface for 30 seconds before compounding.	*Compliant*
PEC cleaned in correct order of top ,back, sides, racks/poles, items on deck, deck.	*Compliant*

Environmental Monitoring: Certification of Ante and Buffer Rooms

All ISO Class 5 PEC and ISO Class 7 and/or ISO Class 8 rooms have been certified as required.	*Compliant*
Review report from certifier. **Date:** *06/10/2019* **Certifier:** *ENV*	*Compliant*
Certification done to CETA guidelines, CAG-003-2006, or similar.	*Compliant*
Certifier's equipment calibrated to manufacturer standards.	*Compliant*
Ante room has HEPA filtered air certified to ISO Class 8 for non-hazardous compounding.	*Compliant*
Ante room has HEPA filtered air certified to ISO Class 7 for hazardous compounding.	*Compliant*
Buffer room has HEPA filtered air certified to ISO Class 7.	*Compliant*
ISO Class 7 ante room, minimum of 30 ACPH. **ACPH:** *35*	*Compliant*
ISO Class 8 ante room, recommended 20 ACPH. **ACPH:** *24*	*Compliant*
ISO Class 7 non-hazardous buffer room, minimum of 30 ACPH with at least 15 from outside source. **ACPH:** *43*	*Compliant*
ISO Class 7 hazardous buffer room, minimum of 30 ACPH. **ACPH:** *45*	*Compliant*
Smoke test performed in PEC in direct compounding area to demonstrate unidirectional airflow under dynamic conditions.	*Compliant*
Differential pressure measured to be at least positive 0.02 inch water column from ante room to general pharmacy with door closed.	*Compliant*

Environmental Monitoring: Certification of Ante and Buffer Rooms *(continued)*

Differential pressure measured to be at least positive 0.02 inch water column from buffer room to ante room with door closed.	*Compliant*
Differential pressure measured to be at least negative 0.01 inch water column from buffer room to positive pressure ISO 7 ante room with door closed.	*Compliant*
If no physical separation of ante and buffer room, displacement airflow measured requiring air velocity of 40 feet/minute or more from buffer area across LOD into ante room.	*N/A*
ISO Class 5 areas not more than 3,520 particles per cubic meter of air, taken under dynamic conditions.	*Compliant*
ISO Class 7 areas not more than 352,000 particles per cubic meter of air, taken under dynamic conditions.	*Compliant*
ISO Class 8 areas not more than 3,520,000 particles per cubic meter of air, taken under dynamic conditions.	*Compliant*
Room HEPA filters leak tested and repaired if needed.	*Compliant*
PEC HEPA filters leak tested and repaired if needed.	*Compliant*
PEC airflow velocity measured.	*Compliant*
Documentation of viable air and surface sampling shall include date and time of sampling.	*Compliant*
Documentation of viable air and surface sampling shall include sampling shall include sample locations.	*Compliant*
Documentation of viable air and surface sampling shall include method of collection.	*Compliant*
Documentation of viable air and surface sampling shall include frequency of sampling.	*Compliant*
Documentation of viable air and surface sampling shall include volume of air sampled.	*Compliant*
Documentation of surface sampling shall include size of surface sampled, 24-30 cm2.	*Compliant*
Documentation of viable air and surface sampling shall include time of day in relationship to compounding.	*Compliant*
Documentation of viable air and surface sampling shall include action levels.	*Compliant*
Viable air sampling performed using active impaction device with appropriate growth media to support bacteria and for high risk compounding fungus, at least every 6 months in all ISO classified areas using 400 – 1000 L of air per sample.	*Compliant*
Viable air microbial action levels for ISO Class 5: 1000 liters > 1 CFU/m3 or 400 liters > 1CFU/m3.	*Compliant*

Environmental Monitoring: Certification of Ante and Buffer Rooms *(continued)*

Viable air microbial action levels for ISO Class 7: 1000 liters, > 10 CFU/m3 or 400 liters, > 4CFU/m3	*Compliant*
Viable air microbial action levels for ISO Class 8: 1000 liters, > 100 CFU/m3 or 400 liters, > 40 CFU/m3	*Compliant*
Viable surface sampling performed periodically on direct compounding areas, buffer and ante rooms, pass thru and surfaces likely to be contaminated, as applicable, using media supplemented with neutralizing effects of disinfecting agents (TSA with lecithin & Polysorbate 80) and done at the conclusion of compounding.	*Compliant*
Surface microbial action levels for ISO Class 5, less than 3 CFU/m3.	*Compliant*
Surface microbial action levels for ISO Class 7, less than 5 CFU/m3.	*Compliant*
Surface microbial action levels for ISO Class 8, less than 100 CFU/m3.	*Compliant*
All CFUs analyzed down to the genus with mold, yeast, coagulase positive Staph, gram negative rods requiring immediate Investigation.	*Compliant*
Exceeded action levels should prompt a re-evaluation of adequacy of personnel work practices, cleaning, operational procedures and/or air efficiency and require an investigation into the source of contamination.	*Compliant*

Environmental Monitoring: Certification of PEC

All ISO Class 5 PECs have been certified as required.	*Compliant*
Review report from outside agency.	*Compliant*
Certification done to CETA guidelines, CAG-003-2006, or similar.	*Compliant*
Certifiers equipment calibrated to manufacturer standards.	*Compliant*
Smoke test performed in PEC in direct compounding area to demonstrate unidirectional airflow under dynamic conditions.	*Compliant*
Differential pressure measured to be at least 0.02 inches water column from ante chamber to general pharmacy area.	*Compliant*
Differential pressure measured to be at least 0.02 inches water column from main chamber to ante chamber.	*Compliant*
ISO Class 5 areas not more than 3,520 particles per cubic meter of air, taken under dynamic conditions.	*Compliant*
PEC HEPA filters leak tested and repaired if needed.	*Compliant*
PEC airflow velocity measured.	*Compliant*

Environmental Monitoring: Certification of PEC *(continued)*

Documentation of viable air and surface sampling shall include date and time of sampling.	*Compliant*
Documentation of viable air and surface sampling shall include sample locations.	*Compliant*
Documentation of viable air and surface sampling shall include method of collection.	*Compliant*
Documentation of viable air and surface sampling shall include frequency of sampling.	*Compliant*
Documentation of viable air sampling shall include volume of air sampled.	*Compliant*
Documentation of surface sampling shall include size of surface sampled, 24-30 cm2.	*Compliant*
Documentation of viable air and surface sampling shall include time of day in relationship to compounding.	*Compliant*
Documentation of viable air and surface sampling shall include action levels.	*Compliant*
Viable air sampling performed using active impaction device with appropriate growth media to support bacteria and for high risk compounding fungus, at least every 6 months in all ISO classified areas using 400 – 1000 liters of air per sample.	*Compliant*
Viable air microbial action levels for ISO Class 5: 1000 liters > 1 CFU/m3 or 400 liters > 1CFU/m3.	*Compliant*
Viable surface sampling performed periodically on direct compounding areas using media supplemented with neutralizing effects of disinfecting agents (TSA with lecithin & Polysorbate 80) and done at the conclusion of compounding.	*Compliant*
Surface microbial action levels for ISO Class 5, less than 3 CFU/m3.	*Compliant*
All CFUs analyzed down to the genus with mold, yeast, coagulase positive Staph, gram negative rods requiring immediate investigation.	*Compliant*
Exceeded action levels should prompt a re-evaluation of adequacy of personnel work practices, cleaning, operational procedures and/or air efficiency and require an investigation into the source of contamination.	*Compliant*

Compounding Procedures

Documentation of equipment maintenance and calibration logs.	*Compliant*
Objects that shed prohibited from buffer room or compounding area of CAI/CACI: pencils, cardboard, paper towels, cotton gauze pads.	*Compliant*
Essential paper products (syringe overwrap, work records in protective plastic sleeves) are wiped down with 70% sIPA in ante room before bringing into buffer room or before placing in the ante chamber of CAI/CACI.	*Compliant*

Compounding Procedures *(continued)*

Required supplies wiped down with 70% sIPA (or removing outer wrap) as item introduced into aseptic work space.	*Compliant*
Syringes, needles, tubing opened only In ISO Class 5 PEC.	*Compliant*
Personnel use correct aseptic technique, compounding in first air.	*Compliant*
Personnel routinely inspecting sterile gloves for wear and tear and replace as necessary.	*Compliant*
Personnel routinely disinfecting sterile gloves with 70% sIPA prior to entering and when re-entering ISO Class 5 area and touching non-sterile objects.	*Compliant*
Personnel ascertain CSP ingredients are correct by looking at label and doing unit by unit inspection of product before using.	*Compliant*
Rubber stoppers of vials/bottles and ampules disinfected with 70% sIPA prior to introducing needle/breaking ampule, waiting 10 seconds for 70% sIPA to dry.	*Compliant*
Contents thoroughly mixed and inspected for particulate matter, incompatibility or other issues.	*Compliant*
Before dispensing CSP, clarity is visually confirmed. Identity and amounts of ingredients, procedures to prepare, sterilize, and specific release criteria are reviewed to assure accuracy and completeness.	*Compliant*
Opened single dose ampules must be discarded immediately.	*Compliant*
Single dose containers opened in worse than ISO Class 5 used within 1 hour then discarded, with time first used/discard time documented on container.	*Compliant*
Single dose containers opened in ISO Class 5 used within 6 hours then discarded, with time first used/discard time documented on container.	*Compliant*
MDV used for 28 days, or as specified by manufacturer, once punctured, with date first used/discard date documented on MDV.	*Compliant*
Compound record is required.	*Compliant*
Appropriate procedures and packaging followed for each step.	*Compliant*
Pharmacist verification of steps performed by technicians by visual inspection.	*Compliant*
Documentation of compounding accuracy by 2nd person in addition to compounder if more than one person is compounding, to ensure proper measurement, reconstitution, component usage.	*Compliant*
Name and quantity of each component on batch labels.	*Compliant*
Date and time preparation compounded (may be internal reference number) on batch labels.	*Compliant*

Compounding Procedures *(continued)*

Verifying pharmacist identifier on batch labels.	*Compliant*
BUD on batch labels. Cannot use exp/expiration. May use: Use Before/Discard After/Administer By, etc.	*Compliant*
Auxiliary labels, ie packaging and labeling of hazardous CSP, on batch lables.	*Compliant*
Standard label requirements on patient specific labels to include date of dispensing, and pharmacy name, address if CSP will leave the premises.	*Compliant*
Verifying pharmacist identifier on patient specific labels.	*Compliant*
BUD on patient specific labels. Cannot use exp/expiration. May use: Use Before/Discard After/Administer By, etc.	*Compliant*
Flow rate, if applicable, on patient specific labels.	*Compliant*
Auxiliary labels, ie packaging & labeling of hazardous CSP, on patient specific labels.	*Compliant*
Directions for use, including infusion rate, on patient specific labels.	*Compliant*
Required controlled substances transfer warnings, where applicable, on patient specific labels.	*Compliant*
Identity of dispensing pharmacist on patient specific labels.	*Compliant*
Storage requirements, when applicable, on patient specific labels.	*Compliant*
If redispense CSPs, must ensure sterility, purity and stability of CSP and BUD cannot be changed unless retested.	*Compliant*
Check for container and closure integrity, done after compounding and if stored, before dispensing.	*Compliant*
Compounding accuracy documented by verification of steps.	*Compliant*
Verification of identity and quantity verified by reconciliation of components.	*Compliant*
Labels verified as being correct.	*Compliant*

Continuous Quality Improvement

Share data with staff.	*Compliant*
Track and trend data.	*Compliant*
Track complaints from patients and practitioners.	*Compliant*
Formalized in writing.	*Compliant*

Continuous Quality Improvement *(continued)*

Consideration of all aspects of preparation and dispensing including environmental testing and verification of results.	*Compliant*
Description of specific monitoring and evaluation activities.	*Compliant*
Specification of how results are to be reported and evaluated.	*Compliant*
Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded.	*Compliant*
Delineation of the individuals responsible for each aspect of the program.	*Compliant*

Sterile Compounding of Hazardous Drugs

Personnel who handle, dispose or compound HD are trained and competency is assessed prior to handling HD and annually thereafter. Training shall be a didactic overview and verified by testing specific HD preparation techniques.	*Compliant*
Personnel who compound HD shall be trained in storage, handling and disposal.	*Compliant*
Personnel who compound HD shall be trained in safe aseptic manipulation practices.	*Compliant*
Personnel who compound HD shall be trained in negative pressure techniques when utilizing BSC or CACI.	*Compliant*
Personnel who compound HD shall be trained in correct use of Closed-System Transfer Devices (CSTD), if applicable.	*Compliant*
Personnel who compound HD shall be trained in containment, cleanup and disposal for breakages and spills.	*Compliant*
Personnel who compound HD shall be trained in treatment of personnel contact and inhalation exposure.	*Compliant*
Written confirmation by all compounding personnel of reproductive capability that they understand the risks of handling HD.	*Compliant*
HD are handled with caution at all times using chemo rated gloves during receiving, distributing, stocking, inventorying, preparing for administration, and disposal.	*Compliant*
Personal compounding equipment (PPE) includes gowns with low permeability like polyethylene.	*Compliant*
Personal compounding equipment (PPE) includes face masks.	*Compliant*
Personal compounding equipment (PPE) includes eye protection, as appropriate.	*Compliant*
Personal compounding equipment (PPE) includes hair covers.	*Compliant*

Sterile Compounding of Hazardous Drugs *(continued)*

Personal compounding equipment (PPE) includes shoe covers or dedicated shoes.	*Compliant*
Personal compounding equipment (PPE) includes double gloving with chemo rated gloves, with outer glove being sterile.	*Compliant*
HD CSP are compounded in a BSC or CACI.	*Compliant*
BSC or CACI is located inside an ISO Class 7 area that is physically separate from other areas and is negative pressure of 0.01 inch water column to adjacent positive pressure ISO Class 7 ante room.	*Compliant*
Documentation from CACI manufacturer that the ISO Class 5 environment is maintained under dynamic conditions when not located in an ISO Class 7 environment but must be in a negative pressure room with at least 12 ACPH.	*Compliant*
For low volume exemption, defined by KBOP as 5 HD CSPs/2 week period, may use 2 levels of containment.	*Compliant*
Documentation from manufacturer of recovery time to achieve ISO Class 5 air quality of CACI when turning off/on and when transferring material from ante chamber to main chamber before and during compounding.	*Compliant*
CACI located in low traffic area.	*Compliant*
For CACI, pressures recorded each shift, minimum of daily. Main chamber is at least negative 0.01 inch water column to ante chamber and ante chamber is at least positive 0.02 inch water column to general pharmacy.	*Compliant*
PEC cleaned daily/each shift in correct order of top, back, sides, racks/poles, front inside of BSC shield or CACI, gauntlets in CACI, items on deck, deck, CACI ante chamber in the same order,	*Compliant*
HD shall be stored separately from other inventory.	*Compliant*
HD disposed of in a manner that complies with all Federal and State laws.	*Compliant*

12 Hour BUD

Compounded in an ISO Class 5 LAFW not located in ISO Class 7 room.	*Compliant*
Low risk, non-hazardous, patient specific CSP.	*Compliant*
BUD 12 hours or less, administration begins no later than 12 hours from beginning of compounding.	*Compliant*
Personnel gowns and garbs the same as for a clean room.	*Compliant*
Cleaning of ISO Class 5 LAWF is the same as for an ISO Class 5 LAWF in clean room.	*Compliant*

12 Hour BUD *(continued)*

ISO Class 5 LAWF is segregated compounding area, not near garbage can, sink, window, door.	*Compliant*

Immediate use

Compounding does not take place in ISO Class 5 PEC.	*Compliant*
Low risk, non-hazardous CSP.	*Compliant*
Compounding procedure is continuous not exceeding 1 hour & administration begins no later than 1 hour from start of compounding, if not CSP is discarded.	*Compliant*
During compounding, aseptic technique is followed and if not immediately administered the CSP is under continuous supervision to minimize contact with non-sterile items.	*N/A*
CSP is immediately and completely administered by compounder or witnessed by compounder, if not must be labeled with patient identifier, names and amounts of all components, name or initials of compounder, and exact 1-hour BUD and time.	*N/A*

CAI not Located in ISO Class 7

Documentation from CAI manufacturer the ISO Class 5 environment is maintained under dynamic conditions when not located in an ISO Class 7 environment.	*N/A*
Documentation from CAI manufacturer of recovery time to achieve ISO Class 5 air quality when turn off and on and when transferring material from ante chamber to main chamber before and during compounding.	*N/A*
CAI located in low traffic area.	*N/A*
Documentation from CAI manufacturer compounder Is exempt from garbing.	*N/A*
CAI Pressures documented each shift, minimum of daily. Main chamber at least positive 0.02 inch water column to ante chamber and ante chamber at least positive 0.02 inch water column to general pharmacy.	*N/A*
Daily/shift documented cleaning of CAI, in the following order: top, back, sides, racks/poles, inside front, gauntlets, items on deck, deck, and ante chamber in same order.	*N/A*
Personnel appropriately garbed while cleaning CAI.	*N/A*
All items cleaned and disinfected before placing in ante chamber of CAI.	*N/A*
Temperature is recorded daily.	*N/A*
Controlled storage areas for room temperature is 68 to 77 F or 20 to 25 C.	*N/A*
Controlled storage area for cold temperature is 36 to 46 F or 2 to 8 C.	*N/A*

CAI not Located in ISO Class 7 *(continued)*

Controlled storage area for freezer temperature is -13 to 14 F or -25 to -10 C.	*N/A*

High Risk

Active Pharmaceutical Ingredient (API): Certificate of Analysis on file.	*N/A*
Active Pharmaceutical Ingredient (API): Use USP or NF product and if not, safety and purity established.	*N/A*
Active Pharmaceutical Ingredient (API): Label bears batch or lot number.	*N/A*
Active Pharmaceutical Ingredient (API): Label bears expiration date, if not, an expiration date of no more than 1 year from date of receiving is assigned.	*N/A*
Pharmacy marks API with date received.	*N/A*
If pharmacy puts API in smaller container for ease of use, container bears name of API.	*N/A*
If pharmacy puts API in smaller container for ease of use, container bears date API was received.	*N/A*
If pharmacy puts API in smaller container for ease of use, container bears date API was transferred.	*N/A*
If pharmacy puts API in smaller container for ease of use, container bears batch or lot number of API.	*N/A*
If pharmacy puts API in smaller container for ease of use, container bears expiration date from manufacturer or pharmacy assigned expiration date of no more than 1 year from date of receiving.	*N/A*
APIs stored in tightly closed containers under temperature, humidity and lighting conditions per official monograph or suppliers.	*N/A*
Pre-sterilization procedures for high risk CSP, weighing and mixing, shall be completed in no worse than ISO Class 8 environment.	*N/A*
Appropriate sterilization methods used and documented.	*N/A*
Terminal sterilization of non-sterile empty vials or stoppers/closures used and documented.	*N/A*
Pre-filter with 1.2 micron to remove large particles, if needed.	*N/A*
Filtration performed in ISO Class 5 environment.	*N/A*
Documentation 0.2/ 0.22 micron sterile, non-pyrogenic microporous membrane filter is chemically/physically compatible with CSP.	*N/A*
Filtration is completed rapidly without filter replacement.	*N/A*

High Risk *(continued)*

Filter integrity testing is performed and documented for each filter used with each batch sterilized by filtration.	*N/A*
Written documentation of description of steam sterilization includes conditions and duration for specific CSP.	*N/A*
Prior to sterilizing, plastic, glass and metal devices are tightly wrapped in low particle shedding paper or fabric or sealed in envelopes that prevent post-sterilization microbial penetration.	*N/A*
Autoclave allowed to reach 121 C before starting sterilization process.	*N/A*
Usual expose to 121 C at 15 psi for 20 – 60 minutes. Maintains log of temperature and exposure time for each steam sterilized CSP.	*N/A*
Ensures steam contacts all ingredients and surfaces to be sterilized.	*N/A*
Autoclave was mapped.	*N/A*
Effectiveness of steam sterilization is verified each time using biological indicators (BI) and temperature-sensing devices.	*N/A*
For dry heat sterilization, heat filtered air is evenly distributed throughout the chamber with a blower.	*N/A*
Dry heat oven is equipped with system for controlling temperature and exposure period and has been mapped.	*N/A*
Sufficient space is left between materials to allow circulation of hot air.	*N/A*
Written documentation of description of dry heat includes conditions and duration for specific CSP.	*N/A*
Effectiveness of dry heat sterilization is verified each time using biological indicators (BI) and temperature-sensing devices.	*N/A*
For depyrogenation by heat used to render glassware, containers, vials free from pyrogens and viable microbes. Cover tightly with aluminum foil, bake at 250 C for 30 minutes, use immediately or if stored must be ISO Class 7 environment.	*N/A*
For depyrogenation by heat written documentation of description of cycle and duration for specific load items.	*N/A*
For depyrogenation by heat effectiveness of cycle is verified using Endotoxin Challenge Vials (ECVs) with bacterial endotoxin testing performed on ECVs to verify the cycle is capable of achieving a 3 log reduction in endotoxins.	*N/A*
If depyrogenated glassware, containers, and/or vials are not used immediately, must be kept tightly covered with aluminum foil and stored in an ISO 7 environment.	*N/A*

High Risk *(continued)*

Other methods of sterilization are used with documented procedures and validation performed.	*N/A*

Extending BUD and Sterility Testing

Sterility testing for both bacteria and fungus performed each time BUD is extended beyond USP guidelines.	*N/A*
Sterility testing performed on high risk CSP prepared in groups of more than 25 identical containers.	*N/A*
Sterility testing performed on high risk CSP exposed longer than 12 hours at 2-8C (36-46F) or longer than 6 hours at warmer than 8C (46F) before sterilization.	*N/A*
Sterility testing is done using membrane filtration (preferred method) or direct inoculation per USP <71>.	*N/A*
Appropriate number of CSPs tested for sterility per UPS <71> for parenterals: less than 100 units, test 10% or 4 units, whichever is greater; for 100-500 units, test 10 units; and for greater than 500 units, test 2% or 20 units, whichever is less.	*N/A*
Appropriate number of CSPs tested for sterility per UPS <71> for large volume parenterals: 2% or 10 containers, whichever is less.	*N/A*
Appropriate number of CSPs tested for sterility per UPS <71> for non-parenterals (eye drops, inhalations): less than 200 units, test 5% or 2 units, whichever is greater; for 200 or more units, test 10 units; and if packaged as unit dose, use parenteral testing numbers.	*N/A*
Bacterial endotoxin testing performed on high risk CSP if prepared in groups of more than 25 identical containers.	*N/A*
Bacterial endotoxin testing performed on high risk CSP if exposed longer than 12 hours at 2-8C (36-46F) or longer than 6 hours at warmer than 8C (46F) before sterilization.	*N/A*
CSP quarantined until results of sterility and endotoxin tests received or if dispensed before receiving results, written procedure requiring daily observation of incubating CSPs and immediate recall when evidence of growth. Patient and prescriber notified of potentially contaminated CSP and potential risk.	*N/A*
Positive sterility test results promptly investigated including aseptic technique, environmental control, etc. to identify source of contamination and correct the issue.	*N/A*
Stability data documented to support extended BUD, either from literature or testing.	*N/A*
Method suitability test performed on CSP for stability data derived from testing.	*N/A*
If potency testing is performed, strength must be within 10% of stated potency.	*N/A*

Transporting CSP Outside Facility

P&P for packing containers specifying which to use.	*N/A*
P&P for insulating and stuffing materials specifying which to use.	*N/A*
Written instructions to patients how to safely open containers of CSP.	*N/A*
Ascertain temperature of CSP during transit.	*N/A*
Specific handling and exposure instructions on the exteriors of containers packed with CSPs.	*N/A*
Periodic review of delivery performance of couriers to ascertain CSPs are being efficiently and properly transported.	*N/A*
Provide CSP labeling that includes clearly readable BUDs, storage instructions, and disposal information for out of date units.	*N/A*
Ascertain each patient is able to store CSP properly, including use of properly functioning refrigerator or freezer if needed.	*N/A*

Board Approved Waivers

Board has approved a waiver for non-hazardous sterile compounding.	*N/A*
Board has approved a waiver for hazardous sterile compounding.	*N/A*

Inspector's Signature

I have completed this inspection in accordance with the statutes and administrative codes.

Inspector: *Katie Busroe*

Pharmacist's Signature

I have read and understand the statutes and administrative codes. I acknowledge that the items noted in this report have been discussed with me. I understand that if I disagree with any of the deficiencies cited, that I have the right to refute them on this report or and other form that I choose to send to the department.

Pharmacist: *B. Steven Hart*