



## STERILE COMPOUNDING INSPECTION REPORT

NAME/ADDRESS OF PHARMACY	LICENSE NUMBER	INSPECTION DATE
	PHARMACIST-IN-CHARGE	PIC LICENSE NO
	RISK LEVEL <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	

**Inspector:**

**Acknowledged By:**

*This report is based solely on the inspector's observations of a random sampling of the pharmacy's activities.  
 Licensees should review Missouri law to ensure compliance*

### GENERAL

	Y	N	N/A
Compounding is completed according to the appropriate risk level [20 CSR 2220-2.200(1)(GG)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sterile compounding policies and procedures available, encompass all aspects of compounding, and are reviewed on an annual basis [20 CSR 2220-2.200(2)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pharmacist verification occurs prior to the release of the final compounded preparation [20 CSR 2220-2.200(14)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Every sterile compound is labeled appropriately and has an assigned beyond-use date [20 CSR 2220-2.200(12)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Point-of-care assembled systems are assembled in a primary engineering control and assigned activated and non-activated beyond-use dates when required [20 CSR 2220-2.200(16)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sterile preparations are packaged, stored, dispensed, and distributed in a manner that will maintain the preparation's chemical and microbiological stability [20 CSR 2220-2.200(15)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Observations

**PERSONNEL TRAINING AND ASSESSMENT**

	Y	N	N/A
Prior to compounding, personnel receive initial didactic/experiential training and pass an aseptic technique skill assessment (visual observation of aseptic competencies and 3 media fill tests) [20 CSR 2220-2.200(10)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aseptic technique skill assessment (visual and media fill) is completed annually or semi-annually according to risk level and reevaluations completed, if required. [20 CSR 2220-2.200(10)(C)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Media fill testing complies with USP Chapter 797's recommended procedures [20 CSR 2220-2.200(10)(B)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Media fill testing simulates the most challenging or stressful conditions and is appropriate for the risk level [20 CSR 2220-2.200(10)(B)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Observations**

**HAND HYGIENE AND GARBING**

	Y	N	N/A
Hands are properly washed prior to donning gloves [20 CSR 2220-2.200(9)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Personnel in the controlled/buffer area are garbed appropriately [20 CSR 2220-2.200(8)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sterile gloves are worn for risk level 2 and 3 activity [20 CSR 2220-2.200(8)(B)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Observations**

**COMPOUNDING PROCEDURES**

	Y	N	N/A
Gloves are disinfected prior to use and frequently while compounding [20 CSR 2220-2.200(8)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Talking and movement is kept to a minimum while compounding [20 CSR 2220-2.900(9)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Compounding personnel demonstrate proper use of first air [20 CSR 2220-2.200(9)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aseptic technique is used to avoid touch contamination of critical sites [20 CSR 2220-2.200(9)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Appropriate critical sites are properly disinfected prior to needle entry [20 CSR 2220-2.200(7)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Materials are wiped down prior to placement in the primary engineering control [20 CSR 2220-2.200(9)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Furniture, carts, supplies and equipment are disinfected prior to entry into ISO classified area [20 CSR 2220-2.200(7)(C)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
All opened vials/containers are labeled with the appropriate in-use time [20 CSR 2220-2.200(9)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Calibration results for automated compounding devices are reviewed by a pharmacist [20 CSR 2220-2.200(5)(D)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pharmacist verification occurs for data entered into any automatic compounder before processing begins [20 CSR 2220-2.200(9)(B)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Observations**

**FACILITIES AND EQUIPMENT**

	Y	N	N/A
Controlled/buffer area(s) are clean and maintained appropriately [20 CSR 2220-2.200(7)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tacky mats are prohibited in the controlled area or any ISO classified area [20 CSR 2220-2.200(7)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Removal of trash from the controlled/buffer area is performed at least daily [20 CSR 2220-2.200(4)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A sink with hot and cold water is near, but not in, the controlled/buffer area [20 CSR 2220-2.200(5)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Drugs and supplies are stored above the floor [20 CSR 2220-2.200(4)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Removal of drugs and supplies from boxes is performed outside the controlled/buffer area [20 CSR 2220-2.200(4)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Particle shedding items and unnecessary supplies are kept out of the controlled/buffer area [20 CSR 2220-2.200(7)(C)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sterile preparations are being prepared in an ISO Class 5 primary engineering control [20 CSR 2220-2.200(5)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Primary engineering control(s) are placed in the appropriate environment according to risk level [20 CSR 2220-2.200(5)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If no ISO 7 buffer area, the controlled area is separated from other operations with a line of demarcation [20 CSR 2220-2.200(1)(I)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Observations**

**CLEANING AND DISINFECTION**

	Y	N	N/A
Primary engineering control(s) are cleaned/disinfected appropriately: daily with a germicidal agent followed by sterile isopropyl alcohol, properly documented [20 CSR 2220-2.200(17)(E)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Buffer/controlled area is cleaned/disinfected appropriately: floors daily, counters/work surfaces daily, ceiling/walls/storage shelving monthly, properly documented [20 CSR 2220-2.200(17)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sterile water for irrigation is used to dilute germicidal agents (if applicable) that are used in the primary engineering control(s) [20 CSR 2220-2.200(17)(E)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The appropriate contact time for disinfectants is utilized when cleaning [20 CSR 2220-2.200(17)(C)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
All cleaning tools are low-lint and dedicated for use in the controlled/ISO classified areas [20 CSR 2220-2.200(17)(D)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If compounding occurs less frequently than the cleaning timeframes, cleaning is performed before each compounding session [20 CSR 2220-2.200(17)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Observations**

<b>ENVIROMENTAL MONITORING</b>	Y	N	N/A
Primary and secondary engineering controls are certified every 6 months and when relocated or major service occurs [20 CSR 2220-2.200(5)(E)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Prefilters are inspected and replaced according to manufacturer's specifications [20 CSR 2220-2.200(5)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Primary and secondary engineering certification results are reviewed by a pharmacist [20 CSR 2220-2.200(5)(E)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Environmental air monitoring is conducted and documented for all ISO classified areas every 6 months [20 CSR 2220-2.200(18)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Risk level 2: Environmental surface monitoring is conducted and documented for all ISO classified areas every 6 months [20 CSR 2220-2.200(18)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Observations</b>			
<input type="text"/>			

<b>CYTOTOXIC COMPOUNDING</b>	Y	N	N/A
Cytotoxic drugs are compounded in a vertical flow, Class II biological safety cabinet or CACI [20 CSR 2220-2.200(19)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Appropriate protective apparel is worn while compounding cytotoxic drugs [20 CSR 2220-2.200(19)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Appropriate safety and containment techniques are maintained for cytotoxic drugs such as decontamination and spill kits [20 CSR 2220-2.200(19)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Appropriate disposal of cytotoxic waste [20 CSR 2220-2.200(19)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Observations</b>			
<input type="text"/>			

<b>RECORDS</b>	Y	N	N/A
Single and batch preparation compounding records accurately maintained [20 CSR 2220-2.200(11)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Refrigerator and freezer temperatures are documented daily [20 CSR 2220-2.200(4)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Incubator temperatures are documented appropriately [20 CSR 2220-2.200(4)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Calibration records are maintained for automated compounders or pumps utilized during compounding [20 CSR 2220-2.200(5)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If pressure differential monitor(s) present, results are recorded daily [20 CSR 2220-2.200(5)(F)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Required records and documentation maintained for two years [20 CSR 2220-2.200(11)(C)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Observations</b>			
<input type="text"/>			

<b>INVESTIGATIONS AND NOTIFICATIONS</b>	Y	N	N/A
Remedial investigation(s) were conducted when required [20 CSR 2220-2.200(20)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
All affected areas of remedial investigation were resampled prior to further compounding [20 CSR 2220-2.200(20)(A)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The Board was notified of any highly pathogenic microorganisms, if detected [20 CSR 2220-2.200(20)(B)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Adverse events/complaints documented and investigated [20 CSR 2220-2.400(8)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recalls and prescriber/patient/Board notifications conducted when required [20 CSR 2220-2.200(21)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Observations</b>			
<input type="text"/>			

<b>RISK LEVEL 3 COMPOUNDING</b>	Y	N	N/A
Personnel training is specific to risk level 3 activities (sterilization, end-preparation testing, etc.) [20 CSR 2220-2.200(3)(C)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Environmental surface monitoring is conducted and documented for all ISO classified areas every 30 days [20 CSR 2220-2.200(18)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-sterile equipment is sterilized before it comes into contact with the final sterilized preparation [20 CSR 2220-2.200(5)(C)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-sterile components are compendial grade or have a certificate of analysis [20 CSR 2220-2.200(9)(C)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Preparation records include sterilization records and quarantine records [20 CSR 2220-2.200(11)(B)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sterilization methods are USP recognized and appropriate for preparation [20 CSR 2220-2.200(9)(C)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
All risk level 3 sterile preparations are tested for sterility according to USP 71 [20 CSR 2220-2.200(14)(C)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
All risk level 3 parenteral preparations are tested for pyrogenicity (endotoxins) according to USP 85 or 151 [20 CSR 2220-2.200(14)(C)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Preparations with a BUD >30 days have laboratory validation to support the stability and potency [20 CSR 2220-2.200(13)(B)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Risk Level 3 preparations shall at a minimum remain Risk Level 3 for the life of the preparation [20 CSR 2220-2.200(5)(C)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Finished preparations awaiting end-preparation testing results are quarantined appropriately [20 CSR 2220-2.200(14)(C)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If a preparation is released prior to testing results, all emergency dispensing procedures are followed and documented [20 CSR 2220-2.200(1)(N)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A recall and sufficient investigation was conducted for any failed end-preparation testing [20 CSR 2220-2.200(21)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Observations</b>			
<input type="text"/>			

***Additional Sterile Compounding Observations:***

***Additional Sterile Compounding Comments***