STERILE COMPOUNDING PHARMACY INSPECTION REPORT
North Carolina Board of Pharmacy
Investigations and Inspections

6015 Farrington Rd. Suite 201
Chapel Hill, NC 27517-8822
919-246-1050

Firm Name:		**Permit:**	**Date:**	**Case #:**
Address:		**RPh. Providing Info. & License #:**		
		RPh. Mgr. & License #		
# of RPhs.:	**# of Techs:**	**Rx Volume:**		**Hours of Operation:**

Sterile Compounding Level	
☐	Low Risk
☐	Low Risk - 12 hr
☐	Immediate Use
☐	Medium Risk
☐	High Risk
☐	Hazardous or NIOSH Listed

Federal Regulations Prohibiting Compounding for Office Use Can Be Found Under The Drug Quality and Security Act, Section 503A and 503B

#	General Information	Yes	No	N/A	Comments
1.	Does this facility compound preparations for office use? (i.e. medications compounded not patient specific pursuant to a valid prescription.)	○	○	○	
2.	Does the pharmacy compound medications that are also available commercially? If yes, does the pharmacy compound the medication in a way that is significantly different from the commercially available product? Is there a documented clinical indication for the compounded medication or the use of a different "vehicle" ?	○	○	○	
3.	Does the pharmacy ship compounded medication into other states? Document out of state licenses.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Finding
Facility Design					
1	PEC ISO 5 located in Buffer with anteroom (solid walls) Buffer maintains ISO 7	○	○	○	
2	Pressure differential 0.02- 0.05 between rooms - must have magnahelix or pressure gauge & documented daily	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Finding
Facility Design					
3	PEC ISO 5 located in Buffer without anteroom - must have 40 FPM or 0.2 meters/second airflow across line of demarcation (need meter) - only low & medium risk allowed. Needs to be documented	○	○	○	
4	PEC ISO 5 in non-controlled room - segregated - 12hr BUD only	○	○	○	
5	No Ledges	○	○	○	
6	Buffer area well lighted	○	○	○	
7	Maintains comfortable temperature	○	○	○	
8	Adequate HEPA filtered air is supplied to the buffer and ante areas to meet 30 ACH	○	○	○	
9	Only the furniture, equipment, supplies and other material required for the compounding activities are brought into the area and they are non-permeable, non-shedding, cleanable, and resistant to disinfectants; before such items are brought into the area, they are cleaned and disinfected	○	○	○	
10	Wall to floor coved or caulked to avoid cracks and crevices where dirt can accumulate.	○	○	○	
11	Buffer area has no sink or floor drain	○	○	○	
12	Anteroom with sink on Clean side of "Line of Demarcation"	○	○	○	
13	Anteroom with sink on "dirty" side of Line of Demarcation.	○	○	○	
14	Anteroom with sink external to Clean room. **NOTE:** Hand wash done prior to booties, hairnet, mask beinng donned. Then the use of waterless alcohol based scrub with continuous activity must be used prior to gown/coverall.	○	○	○	
15	Clean room grade ceiling tiles that are impervious	○	○	○	
16	Ceiling tiles caulked	○	○	○	
17	Carts are stainless steel wire or solid shelving with cleanroom casters	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Facility Design cont'd					
18	Storage shelving, counters and cabinets are smooth, impervious, free from cracks and crevices, non-shedding, cleanable and disinfectable; their number, design and manner of installation promotes effective cleaning and disinfection	○	○	○	
19	The surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in the buffer area are smooth, impervious, free from cracks and crevices and non-shedding; the surfaces are resistant to damage by disinfectant agents	○	○	○	
20	No cardboard within the buffer or ante room	○	○	○	
21	Storage kept at a minimum	○	○	○	
22	Trash removed on a regular basis with minimal agitation	○	○	○	
23	Lights have flush mounted smooth surfaces	○	○	○	
24	Penetrations through walls sealed	○	○	○	
25	CAI and CACI placed in an ISO 7 buffer area unless: maintains ISO class 5 during dynamic operations, transfer of ingredients during compounding preparations.	○	○	○	
26	Hazardous compounding in separate room and room negative 0.01 as well as ISO 7 documented daily.	○	○	○	
27	Anteroom between Positive pressure and negative pressure clean rooms must be ISO 7	○	○	○	
28	Low Use Exempetion (3 doses per week) BSC or CACI in non negative pressure with the use of a Closed system transfer device.	○	○	○	
Cleaning and Disinfecting					
29	Cleaning and Disinfecting SOP documented	○	○	○	
30	Cleanliness of facility is evident, no dust on PEC or other equipment	○	○	○	
31	PEC cleaned at the beginning of each shift, before each batch, not longer than 30 minutes if on going compounding, after spills, and when surfaces are contaminated.	○	○	○	
32	Counters and easily cleanable work surfaces cleaned daily	○	○	○	
33	Floors cleaned daily	○	○	○	

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		Yes	No	N/A	
Cleaning and Disinfecting					
34	Walls, Ceilings, and storage shelves cleaned monthly	○	○	○	
35	Use of low shedding wipes.	○	○	○	
36	Use of Sterile 70 % IPA	○	○	○	
37	Use of appropriate disinfectant.	○	○	○	
Certification-ACPH/Filter Integrity					
38	Cleanroom and PEC certifications preformed at-least every six months.	○	○	○	
39	Anteroom has 20 ACPH per CETA guidelines	○	○	○	
40	Presterilization area with Powder containment hood for high risk compounding (weighing and measuring) must be ISO 8 with 20 ACPH. NOTE: Must be fully garbed and gloved and garbing and gloving must be changed prior to entering ISO 7 Clean room.	○	○	○	
41	Buffer area has 30 ACPH (minimum 15 ACPH can be provided by the PEC)	○	○	○	
Cerfication-ACPH/Filter Integrity Cont'd					
42	Supply HEPA Filters leak tested and document-	○	○	○	
43	Each supply HEPA Filter's velocity or ACPH meas-ured and documented individually.	○	○	○	
44	PEC HEPA Filter Leak test preformed and docu-mented.	○	○	○	
45	PEC HEPA Filter air velocity testing preformed and documented	○	○	○	
46	PEC has a dynamic Air pattern Anaylsis (smoke study) preformed and documented.	○	○	○	
Environmental Monitoring—Non Viable					
47	Particle Count of ISO 5 PEC (LAFW,BSC,CAI,CACI) performed every 6 months or more frquently-Note Frequency.	○	○	○	
48	Action Level: not more than 3520 particles 0.5 µm and larger size per cubic meter of air for any LAFW, BSC, CAI, and CACI	○	○	○	
49	Particulate count of ISO7 buffer performed eve-ry 6 months or more frequently - note frequency	○	○	○	
50	Action Level: not more than 352,000 particles of 0.5 µm size and larger per cubic meter of air for	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Environmental Monitoring—Non Viable Cont.					
51	Particulate count of ISO 8 ante performed every	○	○	○	
52	Action Level: not more than 3,520,000 particles or 0.5 µm size and larger per cubic meter of air for any ante-area	○	○	○	
Environmental Monitoring—Viable					
53	Surface Testing of ISO 5 PEC (LAFW,BSC,CAI,CACI) with TSA preformed every 6 months or more frequently. Note Frequency	○	○	○	
54	Surface Testing of ISO 5 PEC with Fungal Specific Media preformed every 6 months or more frequently. Note Frequency (For High Risk Only)	○	○	○	
55	Action level for ISO 5 PEC Surface Testing: >3 CFUs	○	○	○	
56	Surface Testing of ISO 7 Buffer Room with TSA preformed every 6 months or more frequently. Note Frequency	○	○	○	
57	Surface Testing of ISO 7 Buffer Room with Fungal Specific Media preformed every 6 months or more frequently. Note Frequency (For High Risk	○	○	○	
58	Action Level for ISO 7 Buffer Surface Testing: >5CFUs	○	○	○	
59	Surface Testing of ISO 8 Ante Room with TSA preformed every 6 months or more frequently. Note Frequency	○	○	○	
60	Surface Testing of ISO 8 Ante Room with Fungal Specific Media preformed every 6 months or more frequently. Note Frequency (For High Risk Only)	○	○	○	
61	Action Level for ISO 8 Ante room Surface Tesing >100 CFUs	○	○	○	
62	Air Impact Sampling of ISO 5 PEC (LAFW, BSC, CAI, CACI) with TSA preformed every 6 months or more frequently. Note Frequency	○	○	○	
63	Air Impact Sampling of ISO 5 PEC (LAFW, BSC, CAI, CACI) with Fungal Specific Media preformed every 6 months or more frequently. Note Frequency (For High Risk Only)	○	○	○	
64	Action Level for ISO 5 PEC Air Sampling:>1 CFU	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Environmental Monitoring—Viable					
65	Air Impact Sampling of ISO 7 Buffer Room with TSA preformed every 6 months or more fre-	○	○	○	
66	Air Impact Sampling of ISO 7 Buffer Room with Fungal Specific Media preformed every 6 months or more frequently. Note Frequency (For High Risk Only)	○	○	○	
67	Action Level for ISO 7 Buffer Air Sampling:>10 CFUs	○	○	○	
68	Air Impact Sampling of ISO 8 Ante Room with TSA preformed every 6 months or more frequently. Note Frequency	○	○	○	
69	Air Impact Sampling of ISO 8 Ante Room with Fungal Specific Media preformed every 6 months or more frequently. Note Frequency (For High Risk Only)	○	○	○	
70	Acton Level for ISO 8 Ante Room Air Sampling: >100 CFUs	○	○	○	
71	Volume of Air collected is 400-1000 liters	○	○	○	
72	Fingertip testing of Personnel (one plate on each hand) preformed during/after compounding (action level:>3 CFUs combined)	○	○	○	
Compounding Record					
73	Official or assigned name, strength, and dosage form of the preparation;	○	○	○	
74	Master Formulation Record reference for the preparation	○	○	○	
75	Names and quantities of all components	○	○	○	
76	Sources, lot numbers, and expiration dates of components	○	○	○	
77	Total quantity compounded	○	○	○	
78	Name of the person who prepared the preparation, name of the preson who performed the quality control procedures, and name of the compounder who approved the preparation	○	○	○	
79	Date of preparation;	○	○	○	
80	Assigned control or prescription number	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Compounding Record Cont'd					
81	Assigned BUD	○	○	○	
82	Duplicate label as described in the Master Formulation Record	○	○	○	
83	Description of the final preparation	○	○	○	
84	Documentation of any quality control issues and any adverse reactions or preparation problems reported by patient or caregiver	○	○	○	
85	For Terminally Sterilized preparations: Filter intergrity (bubble point) test results, along with lot number and expiration date of the filter, or biological indicator testing for steam sterilization (autoclave), or bacterial endotoxin testing of ECVs for dry heat sterilization	○	○	○	
Master Formulation Records					
86	Official or assigned name, strength, and dosage form of the preparation	○	○	○	
87	Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients (API)	○	○	○	
88	Description of all ingredients and their quantities	○	○	○	
89	Compatibility and stability information, including references when available	○	○	○	
90	Equipment needed to prepare the preparation, when appropriate	○	○	○	
91	Mixing instructions that should include: a. order of mixing b. mixing temperatures or other environmental controls c. duration of mixing d. other factors pertinent to the replication of the preparation as compounded	○	○	○	
92	Sampling labeling information, which shall contain, in addition to legally required information: a.generic name and quantity or concentration of each active ingredient b. assigned BUD c. storage conditions d. prescription or control number, whichever is applicable	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Master Formulation Records Cont'd					
93	Container used in dispensing	○	○	○	
94	Packaging and storage requirements	○	○	○	
95	Description of final preparation	○	○	○	
96	Quality control procedures and expected results	○	○	○	
Sterile BUD—In the absence of sterility testing					
97	Low Risk: 48 hrs Room Temperature; 14 days Refrigerated & 45 days Frozen	○	○	○	
98	Medium Risk: 30 hrs Room Temperature; 9 days Refrigerated & 45 days Frozen	○	○	○	
99	High Risk: 24 hrs Room Temperature; 3 days Refrigerated & 45 days Frozen	○	○	○	
Extended Sterile BUD - with USP <71> compliant sterility testing					
100	Any Literature Used documented	○	○	○	
101	Potency over time testing	○	○	○	
102	Stability indicating assay	○	○	○	
103	Method suitability performed per compound documented	○	○	○	
104	Membrane filtration testing (preferred over direct inoculation)	○	○	○	
105	Equivalent testing to membrane testing	○	○	○	
		Compliant			
#	Requirement	Yes	No	N/A	Comments
	Number of Items to be Tested (per USP<71>)	○	○	○	
106	Parenteral Preparations - Zero - 100 containers - 4 or 10% whichever is **greater**. 101 - 500 containers - 10. 501 or more containers - 20 or 2% whichever is **less** Large Volume - 10 or 2% whichever is **less**	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
	Number of Items to be Tested (per USP<71>)				
107	Antibiotic Solids - Pharmacy bulk packages <5g - 20 Pharmacy bulk packages >5g - 6 Bulks and Blends - See Bulk Solid Products	○	○	○	
108	Ophthalmics or other non-injectable preparations - If product is in single dose containers - same as parenteral; otherwise <200 containers - 2 or 5% whichever is **greater** >200 containers - 10	○	○	○	
109	Bulk Solid Products - Zero - 4 containers - Each container 5 - 50 containers - 4 or 20% whichever is **greater** 51 or more containers - 10 or 2% whichever is **greater**	○	○	○	
Bacterial Endotoxin Testing					
110	All High Risk Level CSPs in batches of >25 identical individual single dose packages	○	○	○	
111	All High Risk Level CSPs in Multiple Dose Vials (MDVs) for adminstration to multiple patients	○	○	○	
112	All High Risk Level CSPs that are exposed longer than 12 hours at 2 - 8 degrees C **OR** exposed longer than 6 hours above 8 degrees C	○	○	○	
Personnel Training File					
113	Documentation of didactic, observational & written testing for:	○	○	○	
114	Calculations	○	○	○	
115	People who fail testing are retrained, re-evaluated, and pass testing prior to resuming compounding	○	○	○	
116	Aseptic Technique (should include observational checklist)	○	○	○	
117	Must pass media fill prior to initiation of compounding then 1 every 12 months for Low & Medium Risk and every 6 months for high risk	○	○	○	
118	High Risk Media fill should mimic processes used in facility	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Personnel Training File Cont'd					
119	Hand cleansing (should include observational checklist)	○	○	○	
120	Gowning, Garbing & Gloving (should include observational checklist	○	○	○	
121	Inspection and final release of preparations	○	○	○	
122	Fingertip test documentation for Glove Fingertip Testing x 3 initially with Zero CFUs, and then 1 every 12 months for Low & Medium Risk and every 6 months for high risk with <3 CFUs	○	○	○	
123	Cleaning and disinfecting of compounding surfaces & facility on Daily and monthly basis (should include observational checklist)	○	○	○	
124	NIOSH regulated compounding - Don appropriate PPEs gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double glove with sterile chemo-type gloves.	○	○	○	
125	Protect personnel and environment from powders and cross contamination by using powder containment	○	○	○	
126	Identify, weigh and measure ingredients	○	○	○	
127	Training in sterilization and depyrogenation techniques such as: autoclaving, sterile filtration, dry heat sterilization and dry heat depyrogenation, etc.	○	○	○	
Note: All SOPs and logs collected during inspection are attached.					

Notes

Notes Continued

Inspector Signature: _____ Date: _____

☐ By Checking this box, I acknowledge that by my signature I have reviewed this inspection report with the investigator.

Pharmacist Signature : _____ Date: _____

Email Address : _____