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 #:**		
Type:		**RPh. Mgr. & License #**		
# of RPhs.:	**# of Techs:**	**Rx Volume/Day:**	**Hours of Operation:**	

YES	NO		
○	○	Does the Facility perform Non-Sterile Compounding? If **NO**, do not answer questions in Non-Sterile Compounding Section	
○	○	Does the Facility perform Sterile Compounding? If **NO**, do not answer questions in the Sterile Compounding Section	
○	○	Does pharmacy ship into other states? (If yes document permits.)	

		Compliant			
#	**Requirement**	**Yes**	**No**	**N/A**	**Comments**
Inspection Items					
1.	90-85.15A (a) - tech must register with the Board within 30 days after the date of completing the training program.	○	○	○	
2.	90-85.15A (c) - 2:1 ratio, if ratio above provide waiver documentation. Any technician above the 2:1 ratio must be certified (document approval date).	○	○	○	
3.	90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection.	○	○	○	
4.	90-85.25 (b) - PM shall report within 10 days any disaster, accident, theft.	○	○	○	
5.	90-85.26 (a) - prescriptions preserved for 3 years. (b) - Documentation of alleged medication errors.	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Inspection Items					
6.	90-85.29 (1) - prescription label shall contain a discard date that is earlier of 1 yr. from date dispensed or manuf's exp. date, whichever is earlier. (2) - not obscure exp. date and storage statement when product dispensed in manuf's original container.	○	○	○	
7.	90-85.32 (a) - prescriptions marked PRN not refilled more than 1 yr. after issue date.	○	○	○	
8.	90-85.47 - Quality Assurance Program	○	○	○	
9.	90-93 (3)(d): Sch. V log book or record of disposition.	○	○	○	
10.	90-106.1 (a) - documentation system of photo ID. Kept on premises or central location for 3 years.	○	○	○	
11.	90-113.52 (b) - pseudoephedrine Products kept behind counter. (c) - record of every purchaser, amount of product in grams. (d) - records kept for two 2 years.	○	○	○	
12.	90-113.54 - posting of sign prohibiting sale of more than 2 pkgs (3.6grams total) of pseudoeph. /day, no more than 3 pkgs (9grams total) within 30-day period.	○	○	○	
13.	90-640 (b) - ID badge	○	○	○	
14.	CFR 201.17- Misbranded drugs: Medications stored in pharmacy should be labeled with an expiration date and manufacturer lot number. Note: Return to stock prescription vial with the pharmacy's own label affixed will not be deemed misbranded	○	○	○	
15.	46.106-134.1 (4)(b)- label lacks any requirement listed in the subsection. (px name, name/add. of pharmacy, disp. rph's name, rx #, fill date of rx, prescriber name, dir. for use, name & strength of drug.)	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Inspection Items					
16.	46.1601 (a)(2)- posted Pharmacy hours. (4)(A-E)- reference library, hard copy or electronic. (5)- lavatory facilities w/ hot and cold running water; clean, orderly and sanitary. (b)(1)- records are readily retrievable. (b)(2)- toll free number on labels of dispensed medications. (e)- pharmacy permit is countersigned by rph-mgr. as represented in the application.	○	○	○	
17.	46.1802 (a) - refills limited to prescriber's orders.	○	○	○	
18.	46.1803 - All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.	○	○	○	
19.	46.1806 - proper documentation and handling of transferred rxs	○	○	○	
20.	46.1818 - label shall list generic name of drug, even if unavailable to dispense or generic is not authorized.	○	○	○	
21.	46.2302 (a)(1-5) - records of dispensing shall be kept for 3 years.	○	○	○	
22.	46.2303 - records of prescription filling and refilling shall be kept for 3 yrs.	○	○	○	
23.	46.2304 (1) - produce sight-readable documents. (3) - RPh. responsible for completeness and accuracy of entries, provides documentation that prescription information entered is correct. (5) - pharmacy has auxiliary recordkeeping system. (7) - current version of drug interactions software is utilized	○	○	○	
24.	46.2305 - To maintain the confidentiality of patients' prescription orders, there must be adequate safeguards or security of the records.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Inspection Items					
25.	46.2502 (a) - PM shall assure that rx meds & cs meds are safe/secure within the pharmacy. (b) - PM is present one-half the hrs. the pharmacy is open or 32 hrs. /wk., whichever is less. (d) - system of inventory recordkeeping and control to detect any shortage or discrepancies of cs meds. (e) - control of all keys to pharmacy. (j) - written disaster plan. (k) - separate from the dispensing stock all drugs more than 6 months out of date.	○	○	○	
26.	46.2504 (a) - effective communication of information to the patient(s). (b) - offer to counsel for all new and transfer pre-scriptions. (g) - Documentation of refusals.	○	○	○	
27.	46.3001 (a) - policy/procedure for all out dated, improperly labeled, adulterated damaged or unwanted drugs or drug containers are destroyed or disposed.	○	○	○	
28.	46.3301 (b) - Current registration of a pharmacy tech shall be readily available for inspection.	○	○	○	
29.	CFR 1301.75 (b) - controlled substances listed in II, III, IV, and V shall be stored in a substantially con-structed cabinet, or disbursed throughout the non-controlled substances	○	○	○	
30.	CFR 1304.04 (2)(h)(1) - inventories and records of Sch. I & II substances maintained separate from all other records (2)(h)(2)- paper prescriptions for Sch. II sub-stances maintained in separate file.	○	○	○	
31.	CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the regis-tered location. (c) - Biennial inventory.	○	○	○	
32.	CFR 1305.05 (a) - power of attorney on file at registered location.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Inspection Items					
33.	CFR 1305.12 (b) - purchaser shall record 1 item on each numbered line. (c) - name/address of supplier on form. Only 1 supplier on any form. (d)- DEA Form 222 properly signed and dated.	○	○	○	
34.	CFR 1305.13 (e) - purchaser must record the number of commercial or bulk containers furnished on each item and dates on which the containers are received.	○	○	○	
35.	CFR 1305.22 Procedure for filling electronic orders. (g) - purchaser receives shipment, purchaser must create a record of the quantity of each item received and date received. Record must be electronically linked to the original order and archived.	○	○	○	
36.	CFR 1305.27 Preservation of electronic orders. (a) purchaser must, for each order filled, retain the original signed order and all linked records for that order for 2 years. Purchaser must also retain all copies of each unaccepted or defective order and each linked statement. (b) supplier must retain each original order filled and the linked records . (Note: 2yrs for Federal Law; 3yrs for NC Law) (c) If electronic order records are maintained on a central server, records must be readily retrievable at the registered location. (Note: 2yrs for Federal Law; 3yrs for NC Law)	○	○	○	
37.	CFR 1306.05 (a) - all cs prescriptions shall bear full name and address of the patient along with date, drug, strength, dosage form, quantity, dirs. for use, and name, address and registration number of practitioner. (d) - computer generated prescription that is printed or faxed must be manually signed	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Inspection Items					
38.	CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the pharmacy complies with all requirements. A Sch. II order signed by the practitioner.	○	○	○	
39.	CFR 1306.14 (a) - prescription vials labeled for Sch. II display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.	○	○	○	
40.	CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner.	○	○	○	
41.	CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable.	○	○	○	
42.	CFR 1306.24 (a) - prescription vials labeled for Sch. III, IV, or V display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.	○	○	○	
43.	CFR 1306.26 (b) - not more than 8oz. of any cs containing opium, nor more than 4oz. of any other cs; not more than 48 dosage units of any such cs containing opium, nor more than 24 dosage units of any other such cs to the same purchaser in any 48-hr. period. (c) - purchaser at least 18 yoa (d) - furnish suitable ID (e) - maintain log containing name and address of purchaser, name and qty. of cs, date of purchase, name or initials of RPh. who dispensed the substance.	○	○	○	
44.	CFR 1311.10 Eligibility to obtain a CSOS digital certificate. (a) - person who signed the most recent DEA registration application or renewal application and a person authorized to sign a registration application. (b) - person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Inspection Items					
45.	CFR 1311.30 Requirements for storing and using a private key for digitally signing orders. (a) - Only the certificate holder may access or use his or her digital certificate and private key. (b) - The certificate holder must provide FIPS-approved secure storage for the private key, as discussed by FIPS 140-2, 180-2, 186-2, and accompanying change notices and annexes, as incorporated by reference in §1311.08. (c) - A certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.	○	○	○	
46.	CFR 1311.35 Number of CSOS digital certificates needed. A purchaser of Schedule I and II controlled substances must obtain a separate CSOS certificate for each registered location for which the purchaser will order these controlled substances.	○	○	○	
47.	CFR 1311.60 Recordkeeping. (a) - supplier and purchaser must maintain records of CSOS electronic orders and any linked records for 2 years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records. (Note: 2yrs for Federal Law; 3yrs for NC Law) (b) - Electronic records must be easily readable or easily rendered into a format that a person can read. Must be made available to the Administration upon request. (c) - CSOS certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate.	○	○	○	

Notes

Non– sterile Compounding Section

Is there a designated pharmacist responsible for non-sterile compounding operations. If yes, Give Name and license number ○ Yes ○ No	Name & License #

#	Requirement	Yes	No	N/A	Comments
General Information					
48.	Does this facility compound preparations for office use? (i.e. medications compounded not patient specific pursuant to a valid prescription.)	○	○	○	
49.	Does the pharmacy compound medications that are also available commercially, (e.g Tadalafil/ Sildenafil)? 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" ?	○	○	○	

Non-Sterile Compounding Levels		
Yes	**No**	
○	○	**Simple**: Making a preparation that has a USP compounding monograph or appears in a peer-reviewed journal that contains specifics on component quantities, compounding procedure, equipment and stability data for the formulation and appropriate Beyond Use Dates (BUD), or Reconstituting or manipulating commercial products that require addition of one or more ingredients as directed by the manufacturer. ***Examples of Non-Sterile Compounding****:* Captopril Oral Solution, Indomethacin Topical Gel and Potassium Bromide Oral Solution.
○	○	**Moderate**: Compounding a preparation that requires special calculations or procedures to determine quantities of components per preparation or per dosage unit. Making a preparation for which stability data is not available for the preparation. ***Examples of Moderate Non-Sterile Compounding****:* morphine sulfate suppositories, diphenhydramine troches, or mixture of two or more manufactured creams when stability of the mixture is not known.
○	○	**Complex**: Making a preparation that requires special training, environment, facilities, equipment and procedures to ensure appropriate therapeutic outcomes. ***Examples of Complex Non-Sterile Compounding****:* transdermal dosage forms, modified-release preparations and suppositories for systemic effects.
○	○	**Hazardous or NIOSH listed**: Any drug identified as carcinogenic, teratogenic, reproductive toxicity, organ toxicity, genotoxicity or any new drug that mimics existing hazardous drugs in structure or toxicity. These drugs are identified in the National Institute for Occupational Safety and Health (NIOSH) publication list.

IF PERMIT IS ONLY PERFORMING SIMPLE NON-STERILE COMPOUNDING—ANSWER5 QUESTIONS 50-57 ONLY
IF PERMIT IS PERFORMING MODERATE, COMPLEX, AND /OR HAZARDOUS/NIOSH — ANSWER ALL QUESTIONS IN THE NON-STERILE SECTION

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Simple Non-sterile Compounding					
50.	**.**2800 USP <795> and <797>. **Simple Non-Sterile Compounding:** Making a preparation that has a USP compounding monograph or appears in a peer-reviewed journal that contains specifics on component quantities, compounding procedure, equipment and stability data for the formulation and appropriate Beyond Use Dates (BUD), or reconstituting or manipulating commercial products that require addition of one or more ingredients as directed by the manufacturer.	○	○	○	
51.	**a)** Official name, strength, and dosage of preparation.	○	○	○	
52.	**b)** Name and quantities of all components.	○	○	○	
53.	**c)** Sources, lot numbers, and expiration dates of components.	○	○	○	
54	**d)** Name of person who compounded and the person verified the preparation.	○	○	○	
55	**e)** Date preparation.	○	○	○	
56	**f)** Assigned BUD.	○	○	○	
57	**2g)** Description of final preparation.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Personnel Training					
58.	Documentation that all personnel that perform compounding are appropriately trained including policy and procedures, compounding documentation, Hazardous drug handling, and compounding technique. This includes pharmacist manager or designated pharmacist	○	○	○	
59.	Documentation that the training includes the operation of any equipment that may be used when preparing compounded products.	○	○	○	
60.	Documentation showing the employee has been trained on the storage, handling, and disposal of Hazardous Drugs.	○	○	○	
61.	Documentation that the training process for the preparation of compounds include demonstration of the compounding procedures, calculations, and finished preparation before being allowed to preform compounding.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Components Selection					
62.	Are Certificates of Analysis (COA) obtained and reviewed for all bulk APIs used for compounding	○	○	○	
63.	Are USP or NF grade components used, if available.	○	○	○	
64.	If USP– NF components are not available does pharmacy use components that are chemically pure, analytical reagent grade, or American Chemical Society certified.	○	○	○	
65.	All substances or components labeled with a batch control number or lot number, and an expiration date.	○	○	○	.
66.	Components that do not have an expiration date are labeled with date received and a conservative expiration date that does not exceed three years.	○	○	○	
67.	Hazardous Bulk components segregated (including hormones).	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Components Selection Cont'd					
68.	Ingredients used for dietary or nutritional supplements meet USP, Food Chemical Codex (FCC), or NF Standards, or does the pharmacy have alternate means to determine if the ingredients meet food-grade quality.	○	○	○	
69.	Compounded medications for Veterinary application labeled to indicate "Veterinary Use "	○	○	○	
70.	There are no preparations made or ingredients used that appear on the FDA list of drugs products withdrawn or removed from the market for safety reasons.	○	○	○	
		Compliant			
#	Requirement	Yes	No	N/A	Comments
Beyond Use Dating					
71.	Documentation on Compounding record of BUD assigned	○	○	○	
72.	Compliance with USP 795: A) For Non aqueous Formulations— the BUD is not later than the time remaining until the earliest expiration date of any API or 6 months which ever is earlier. B) For Water-Containing Oral Formulations—The BUD is not later than 14 days when stored at controlled cold temperatures C) For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations—The BUD is not later than 30 days	○	○	○	
73.	If the beyond-use dates are exceeded the pharmacy must have supporting valid scientific stability information that is directly applicable to the specific preparation (i.e., the same drug concentration range, pH, excipients, vehicle, water content, etc.).	○	○	○	
		Compliant			
#	Requirement	Yes	No	N/A	Comments
Master Formulation Records					
74.	Official or assigned name, strength, and dosage form of the preparation (ISMP guidelines, no Abbreviations).	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Master Formulation Records					
75.	Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients (API)	○	○	○	
76.	Description of all ingredients and their quantities	○	○	○	
77.	Compatibility and stability information, including references when available	○	○	○	
78.	Equipment needed to prepare the preparation, when appropriate	○	○	○	
79.	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	○	○	○	
80.	Sample label 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.	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Compounding Record					
81.	Container used in dispensing	○	○	○	
82.	Packaging and storage requirements	○	○	○	
83.	Description of final preparation	○	○	○	
84.	Quality control procedures and expected results	○	○	○	
85.	Official or assigned name, strength, and dosage form of the preparation; (ISMP guidelines no abbreviations).	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Compounding Record Con't					
86.	Master Formulation Record reference for the preparation .	○	○	○	
87.	Names and quantities of all components.	○	○	○	
88.	Sources, lot numbers, and expiration dates of components.	○	○	○	
89.	Total quantity compounded.	○	○	○	
90.	Name of the person who prepared the preparation, name of the person who performed the quality control procedures, and name of the compounder who approved the preparation.	○	○	○	
91.	Date of preparation.	○	○	○	
92.	Assigned control or prescription number.	○	○	○	
93.	Assigned BUD	○	○	○	
94	Duplicate label as described in the Master Formulation Record.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Compounding Environment					
95.	Results of QC procedures documented (weight range of filled capsules, pH of aqueous liquids, etc).	○	○	○	
96.	Compounding Facility has adequate space that is specifically designated for compounding prescriptions. Space allows for orderly placement of equipment and only one compound at a time.	○	○	○	
97.	Procedures are implemented to prevent cross–contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.	○	○	○	
98.	The compounding area is well lit.	○	○	○	
99.	Pharmacy perform hazardous non-sterile compounding in a ventilated cabinet (Powder Containment Hood).	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Compounding Environment Cont.					
100.	Ventilated Cabinet (Powder Containment Hood) certified or tested according to manufacturer specifications. Documentation required.	○	○	○	
101.	Hood prefilters are checked and replaced regularly.	○	○	○	
102.	Pharmacy has sink located in the compounding area with hot and cold water, soap or detergent, air-driers or single use towels	○	○	○	
103.	Pharmacy has adequate space to wash equipment and utensils including access to water for rinsing.	○	○	○	
104.	Appropriate temperature and humidity monitors maintained and documented.	○	○	○	
105.	Bulk ingredients stored in a clean and sanitary condition.	○	○	○	
106.	Appropriate protective attire (gloves, gowns, mask, etc) are available including appropriate PPE for Hazardous Drug Compounding. (See NIOSH alert)	○	○	○	
107.	Hazardous drugs are stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare worker and other personnel (OSHA regulations and NIOSH Alert).	○	○	○	
108.	Trash is disposed of in a safe and sanitary manner in accordance with state and federal regulations including Hazardous waste.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Compounding Equipment					
109.	Utensils used for compounding are neither reactive nor additive, and therefore will not affect or alter the purity of the compounded preparation.	○	○	○	
110.	Appropriate equipment and utensils are available and cleaned regularly throughout the compounding process. Appropriate cleaning policies and procedures followed.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Compounding Equipment Cont'd					
111.	Scales, balances, or other equipment used for measurement are validated and calibrated at least annually. (See USP 1176)	○	○	○	
112.	The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Finished Preparation Release Checks and Tests					
113.	Is the finished preparation checked to ensure it appears as expected in the master formulation record.	○	○	○	
114.	Final completed preparations assessed for weight, mixing, clarity, odor, consistency, pH, and strength. This is documented.	○	○	○	
115.	There are established written policies and procedures that describe tests or examinations conducted on the compounded preparation to ensure uniformity and integrity.	○	○	○	
116.	Labels on immediate patient specific container need to include in addition to all legally required elements, identifiers for the person preparing the compound and performing the final verification, BUD, an indication that this is a compound, special storage requirements, and appropriate packing and labeling for Hazardous materials	○	○	○	
117.	For Batch preparations (in anticipation of prescriptions) are of appropriate volume, labeled with official name, quantity of all contents, date and time of the preparation, preparer, and verifying RPh, the correct BUD, and any auxiliary labels including appropriate packaging and labeling of hazardous materials.	○	○	○	

#	Requirement	Yes	No	N/A	Comments
Finished Preparation Release Checks and Tests					
118.	Preparations are stored properly prior to dispensing based upon conditions which BUD was assigned.	○	○	○	
119.	Preparations are examined immediate after preparation and prior to dispensing	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Quality Assurance					
120.	Pharmacy has/keeps quality related event reports for compounded products.	○	○	○	
121.	The facility QA program identifies action limits or thresholds and the appropriate follow up mechanism when action limits or thresholds are exceeded including a recall system.	○	○	○	
122.	The pharmacy has a recall system in place to communicate with the patients and physicians regarding affected compounded products.	○	○	○	

Notes

Notes

Sterile Compounding Section

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

Is there a designated pharmacist responsible for sterile compounding operations. If yes, Give Name and license number

○ **Yes** ○ **No**

Name: _____

License #: _____

General Information					
#	**General Information**	**Yes**	**No**	**N/A**	**Comments**
115.	Does this facility compound preparations for office use? (i.e. medications compounded not patient specific pursuant to a valid prescription.)	○	○	○	
116.	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" ?	○	○	○	

		Compliant			
#	**Requirement**	**Yes**	**No**	**N/A**	**Finding**
Facility Design					
117.	PEC ISO 5 in non-controlled room - segregated - 12hr BUD only (Low risk only).	○	○	○	
118.	CAI and CACI placed in an ISO 7 buffer area unless: maintains ISO class 5 during dynamic operations, transfer of ingredients during compounding preparations.	○	○	○	
119.	PEC ISO 5 located in Buffer with anteroom (solid walls) Buffer maintains ISO 7.	○	○	○	
120.	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					
121.	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.	○	○	○	
122.	No Ledges.	○	○	○	
123.	Buffer area well lighted.	○	○	○	
124.	Maintains comfortable temperature.	○	○	○	
125.	Pre-sterilization 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. Cannot be in Buffer.	○	○	○	
126.	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.	○	○	○	
127.	Wall to floor coved or caulked to avoid cracks and crevices where dirt can accumulate.	○	○	○	
128.	Buffer area has no sink or floor drain.	○	○	○	
129.	Clean room grade ceiling tiles that are impervious.	○	○	○	
130.	Ceiling tiles caulked. (Note no gaskets)	○	○	○	
131.	Carts are stainless steel wire or solid shelving with cleanroom casters.	○	○	○	
132.	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.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Facility Design cont'd					
133.	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.	○	○	○	
134.	No cardboard within the buffer or ante room	○	○	○	
135.	Storage kept at a minimum	○	○	○	
136.	Trash removed on a regular basis with minimal agitation	○	○	○	
137.	Lights have flush mounted smooth surfaces	○	○	○	
138.	Penetrations through walls sealed	○	○	○	
139.	Hazardous compounding in separate room and room negative 0.01 as well as ISO 7 documented daily.	○	○	○	
140.	Anteroom between Positive pressure and negative pressure clean rooms must be ISO 7	○	○	○	
141.	Low Use Exemption (3 doses per week) BSC or CACI in non negative pressure with the use of a Closed system transfer device.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Cleaning and Disinfecting					
142.	Cleaning and Disinfecting SOP documented	○	○	○	
143.	Cleanliness of facility is evident, no dust on PEC or other equipment	○	○	○	
144.	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 with sterile IPA	○	○	○	
145.	Counters and easily cleanable work surfaces cleaned daily	○	○	○	
146.	Floors cleaned daily	○	○	○	
147.	Walls, Ceilings, and storage shelves cleaned monthly	○	○	○	
148.	Use of low shedding wipes.	○	○	○	
149.	Use of Sterile 70 % IPA and appropriate disinfectant . (See USP 1072)	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Certification-ACPH/Filter Integrity					
150.	Cleanroom and PEC certifications performed at least every six months.	○	○	○	
151.	Anteroom has 20 ACPH per CETA guidelines.	○	○	○	
152.	Buffer area has 30 ACPH (maximum 15 ACPH can be provided by the PEC).	○	○	○	
153.	HEPA Filters leak tested and documented.	○	○	○	
154.	ACPH measured and documented for all ISO Classified areas.	○	○	○	
155.	PEC HEPA Filter Leak test performed and documented.	○	○	○	
156.	PEC HEPA Filter air velocity testing performed and documented.	○	○	○	
157.	PEC has a dynamic Air pattern Analysis (smoke study) performed and documented. Certification done under dynamic conditions with staff simulating activities.	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Environmental Monitoring—Non Viable					
158.	Particle Count of ISO 5 PEC (LAFW,BSC,CAI,CACI) performed every 6 months or more frequently. Note Frequency.	○	○	○	
159.	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.	○	○	○	
160.	Particulate count of ISO7 buffer performed every 6 months or more frequently. Note frequency.	○	○	○	
161.	Action Level: not more than 352,000 particles of 0.5 µm size and larger per cubic meter of air for any buffer area .	○	○	○	
162.	Particulate count of ISO 8 ante performed every 6 months or more frequently - Note Frequency and Type of Media used (Best practice Bacterial & Fungal growth supported media).	○	○	○	
163.	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.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Environmental Monitoring—Viable					
164.	Does pharmacy have an environmental sampling plan?	○	○	○	
165.	Surface Testing of ISO 5 PEC (LAFW,BSC,CAI,CACI) performed every 6 months or more frequently. Note Frequency and Type of Media used (Best practice Bacterial & Fungal growth supported media).	○	○	○	
166.	Action level for ISO 5 PEC Surface Testing: >3 CFUs.	○	○	○	
167,	Surface Testing of ISO 7 Buffer Room with TSA performed every 6 months or more frequently. Note Frequency and Type of Media used (Best practice Bacterial & Fungal growth supported media.	○	○	○	
168.	Action Level for ISO 7 Buffer Surface Testing: >5CFUs.	○	○	○	
169.	Surface Testing of ISO 8 Ante Room with TSA performed every 6 months or more frequently. Note Frequency and Type of Media used (Best practice Bacterial & Fungal growth supported media).	○	○	○	
170.	Action Level for ISO 8 Ante room Surface Testing >100 CFUs.	○	○	○	
171.	Air Impact Sampling of ISO 5 PEC (LAFW, BSC, CAI, CACI) with TSA performed every 6 months or more frequently. Note Frequency.	○	○	○	
172.	Air Impact Sampling of ISO 5 PEC (LAFW, BSC, CAI, CACI) with Fungal Specific Media performed every 6 months or more frequently. Note Frequency (Required for High Risk Only, best practice for Medium & Low Risk).	○	○	○	
173.	Action Level for ISO 5 PEC Air Sampling:>1 CFU.	○	○	○	
174.	Air Impact Sampling of ISO 7 Buffer Room with TSA performed every 6 months or more frequently. Note Frequency.	○	○	○	
175.	Air Impact Sampling of ISO 7 Buffer Room with Fungal Specific Media performed every 6 months or more frequently. Note Frequency (Required High Risk Only, Best Practice for Medium and Low Risk).	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Environmental Monitoring—Viable					
176.	Action Level for ISO 7 Buffer Air Sampling:>10 CFUs.	○	○	○	
177.	Air Impact Sampling of ISO 8 Ante Room with TSA performed every 6 months or more frequently. Note Frequency.	○	○	○	
178.	Air Impact Sampling of ISO 8 Ante Room with Fungal Specific Media performed every 6 months or more frequently. Note Frequency (Required for High Risk Only, Best Practice for Medium & Low Risk).	○	○	○	
179.	Acton Level for ISO 8 Ante Room Air Sampling: >100 CFUs.	○	○	○	
180.	Volume of Air collected is 400-1000 liters.	○	○	○	
181.	Fingertip testing of Personnel (one plate on each hand) performed during/after compounding (action level:>3 CFUs combined).	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Compounding Record					
182.	Official or assigned name, strength, and dosage form of the preparation	○	○	○	
183.	Master Formulation Record reference for the preparation.	○	○	○	
184.	Names and quantities of all components	○	○	○	
185.	Sources, lot numbers, and expiration dates of components.	○	○	○	
186.	Total quantity compounded	○	○	○	
187.	Name of the person who prepared the preparation, name of the person performed the quality control procedures, and name of the compounder who approved the preparation.	○	○	○	
188.	Date of preparation;	○	○	○	
189.	Assigned control or prescription number	○	○	○	
190.	Assigned BUD	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Compounding Record Con't					
191.	Duplicate label as described in the Master Formulation Record	○	○	○	
192.	Description of the final preparation.	○	○	○	
193.	Documentation of any quality control issues and any adverse reactions or preparation problems reported by patient or caregiver.	○	○	○	
194.	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.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Master Formulation Records					
195.	Official or assigned name, strength, and dosage form of the preparation	○	○	○	
196.	Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients (API).	○	○	○	
197.	Description of all ingredients and their quantities.	○	○	○	
198.	Compatibility and stability information, including references when available.	○	○	○	
199.	Equipment needed to prepare the preparation, when appropriate.	○	○	○	
200.	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	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Master Formulation Records					
201.	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	○	○	○	
202.	Container used in dispensing.	○	○	○	
203.	Packaging and storage requirements.	○	○	○	
204.	Description of final preparation.	○	○	○	
205.	Quality control procedures and expected results.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Sterile BUD—In the absence of sterility testing					
206.	Low Risk: 48 hrs Room Temperature; 14 days Refrigerated & 45 days Frozen.	○	○	○	
207.	Medium Risk: 30 hrs Room Temperature; 9 days Refrigerated & 45 days Frozen.	○	○	○	
208.	High Risk: 24 hrs Room Temperature; 3 days Refrigerated & 45 days Frozen.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Extended Sterile BUD—with USP <71> compliant sterility testing					
209.	Any Literature Used documented.	○	○	○	
210.	Potency over time testing.	○	○	○	
211.	Stability indicating assay.	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Extended Sterile BUD—with USP <71> compliant sterility testing					
212.	Method suitability performed per compound documented.	○	○	○	
213.	Membrane filtration testing (preferred over direct inoculation).	○	○	○	
214.	Equivalent testing to membrane testing.	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Number of Items to be Tested (Per USP <71>)					
215.	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 (give examples of each).**	○	○	○	
216.	Antibiotic Solids - Pharmacy bulk packages <5g - 20 pharmacy bulk packages >5g - 6 . Bulks and Blends - See Bulk Solid Products	○	○	○	
217.	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	○	○	○	
218.	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.**	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Bacterial Endotoxin Testing					
219.	All High Risk Level CSPs in batches of >25 identical individual single dose packages .	○	○	○	
220.	All High Risk Level CSPs in Multiple Dose Vials (MDVs) for administration to multiple patients.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Bacterial Endotoxin Testing					
221.	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.	○	○	○	
		Compliant			
#	Requirement	Yes	No	N/A	Comments
Personnel Training File: Documentation of didactic, observational & writing testing for:					
222.	Calculations (1160) See USP 1160.	○	○	○	
223.	People who fail testing are retrained, re-evaluated, and pass testing prior to resuming compounding.	○	○	○	
224.	Aseptic Technique (should include observational checklist).	○	○	○	
225.	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. All media fills should mimic most complex manipulations of pharmacy regardless of risk level & should be performed when staff is at their worst.	○	○	○	
226.	Hand cleansing (should include observational checklist).	○	○	○	
227.	Inspection and final release of preparations .	○	○	○	
228.	Fingertip test documentation for Glove Fingertip Testing x 3 initially with Zero CFUs, during process GFT, 1 every 12 months for Low & Medium Risk and every 6 months for high risk with <3 CFUs; documentation must include lot, exp., & staff involved.	○	○	○	
229.	Cleaning and disinfecting of compounding surfaces & facility on daily and monthly basis (should include observational checklist).	○	○	○	
230.	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.	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Personnel Training File: Documentation of didactic, observational & writing testing for:					
231.	Protect personnel and environment from powders and cross contamination by using powder containment.	○	○	○	
232.	Identify, weigh and measure ingredients.	○	○	○	
233.	Training in sterilization and depyrogenation techniques such as: autoclaving, sterile filtration, dry heat sterilization and dry heat depyrogenation, etc.	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Personnel Training File: Gowning and Garbing					
234.	Gowning, Garbing, and Gloving should include observational checklist & personnel file.	○	○	○	
235.	Staff removes all outer garments (coats, hats, jackets, scarves, sweaters, and vests).	○	○	○	
236.	Staff removes all cosmetics and all visible jewelry or piercings.	○	○	○	
237.	Staff dons shoe covers, head covers, beard covers (if applicable), and face masks.	○	○	○	
238.	Hand cleansing is performed by cleaning debris under finger nails using a disposable nail pick, and vigorous hand washing to forearms for at least 30 seconds. Use of lint free disposable towels.	○	○	○	
239.	Staff dons gowns that are non-shedding with sleeves that fit snuggly around the wrist and encloses neck. Note: Gowns can be reused for on shift only. Hair covers, shoe covers, beard covers, face mask, and gloves can only be used one time.	○	○	○	
240.	Once inside the buffer, antiseptic hand cleansing is performed using a waterless alcohol based surgical scrub with persistent activity.	○	○	○	
241.	Staff dons sterile powder free gloves.	○	○	○	
242.,	For CAI and CACI sterile gloves must be donned over the gauntlet gloves.	○	○	○	

Notes

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: _____

E-mail Address : _____