NON-STERIILE 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:**

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.

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

		Compliant			
#	Requirement	Yes	No	N/A	Comments
General Information					
2.	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" ?	○	○	○	
		Compliant			
#	Requirement	Yes	No	N/A	Comments
Components Selection					
3.	Are Certificates of Analysis (COA) obtained an reviewed for all bulk APIs used for compounding	○	○	○	
4.	Are USP or NF grade components used, if available.	○	○	○	
5.	If USP– NF components are not available does pharmacy use components that are chemically pure, analytical reagent grade, or American Chemical Society certified.	○	○	○	
6.	Components that do not have an expiration date are labeled with date received and a conservative expiration date that does not exceed three years.	○	○	○	
7.	All substances or Components Labeled with a batch control number or lot number, and an expiration date.	○	○	○	
8.	Hazardous Bulk component segregated (including hormones).	○	○	○	
9.	Do ingredients used for dietary or nutritional supplements meet USP, Food Chemical Codex (FCC), or NF Standards, or does the pharmacy has alternate means to determine if the ingredients meet food-grade quality.	○	○	○	
10.	Are compounded medications for Veterinary application labeled to indication "Veterinary Use "	○	○	○	
11.	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					
12.	Documentation on Compounding record of BUD assigned	○	○	○	
13.	Compliance with USP 795 & 797 minimums unless documentation	○	○	○	
14.	Non-sterile Water containing preparation not later than 14 days refrigerated	○	○	○	
15.	For non-aqueous formulations not later than the earliest expiration date of any API or not later than 6 months.	○	○	○	
16.	When a manufactured drug product is the source for the Active Pharmaceutical Ingredient then the lesser of 25% of remaining expiration date or 6 months.	○	○	○	
17.	For All Other Formulations—The beyond-use date is not later than the intended duration of therapy or 30 days, whichever is earlier.	○	○	○	
18..	If the beyond-use dates are exceeded does the pharmacy 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					
19.	Official or assigned name, strength, and dosage	○	○	○	
20.	Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients (API)	○	○	○	
21.	Description of all ingredients and their quantities	○	○	○	
22.	Compatibility and stability information, including references when available	○	○	○	
23.	Equipment needed to prepare the preparation, when appropriate	○	○	○	
24	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	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Master Formulation Records					
25.	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	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Compounding Record					
26.	Container used in dispensing	○	○	○	
27.	Packaging and storage requirements	○	○	○	
28.	Description of final preparation	○	○	○	
29.	Quality control procedures and expected results	○	○	○	
30.	Official or assigned name, strength, and dosage form of the preparation;	○	○	○	
31.	Master Formulation Record reference for the preparation	○	○	○	
32.	Names and quantities of all components	○	○	○	
33.	Sources, lot numbers, and expiration dates of components	○	○	○	
34.	Total quantity compounded	○	○	○	
35.	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	○	○	○	
36.	Date of preparation;	○	○	○	
37.	Assigned control or prescription number	○	○	○	
38.	Assigned BUD	○	○	○	
39.	Duplicate label as described in the Master Formulation Record	○	○	○	
40.	Description of the final preparation	○	○	○	

#	Requirement	Compliant			Comments
		Yes	No	N/A	
Compounding Environment					
41.	Results of QC procedures documented (weight range of filled capsules, pH of aqueous liquids, etc)	○	○	○	
42.	Does Compounding Facility have adequate space that is specifically designated for compounding prescriptions? Does space allow for orderly placement of equipment	○	○	○	
43.	Only one preparation compounded at a time	○	○	○	
44.	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.	○	○	○	
45.	The compounding are a is well lit.	○	○	○	
46.	Does pharmacy preform hazardous non-sterile compounding in a ventilated cabinet (Powder Containment Hood).	○	○	○	
47.	Ventilated Cabinet (Powder Containment Hood) certified or tested periodically.	○	○	○	
48.	Hood prefilters are checked and replaced regularly.	○	○	○	
49.	Appropriate protective attire (gloves, gowns, mask, etc) are available including appropriate PPE for Hazardous Drug Compounding.	○	○	○	
50.	Does pharmacy have a sink located in the compounding area with hot and cold water, soap or detergent, air-driers or single use towels	○	○	○	
51.	Does pharmacy have adequate space to wash equipment and utensils including access to water for rinsing.	○	○	○	
52.	Are appropriate temperature and humidity monitors maintained and documented.	○	○	○	
53.	Are bulk ingredients stored in a clean and sanitary condition.	○	○	○	
54.	Hazardous drugs are stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare worker ant other personnel (OSHA regulations and NIOSH Alert).	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Compounding Environment Cont.					
55.	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
Personnel Training					
56.	Documentation that all personnel that perform compounding are appropriate trained including policy and procedures, compounding documentation, Hazardous drug handling, and compounding technique.	○	○	○	
57.	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.	○	○	○	
58.	Documentation that the training includes the operation of any equipment that may be used when preparing compounded products.	○	○	○	
59.	Documentation showing the employee has been trained on the storage, handling, and disposal of Hazardous Drugs.	○	○	○	
		Compliant			
#	Requirement	Yes	No	N/A	Comments
Compounding Equipment					
60.	Utensils used for compounding are neither reactive nor additive, and therefore will not affect or alter the purity of the compounded preparation.	○	○	○	
61.	Appropriate equipment and utensils are available and cleaned regularly throughout the compounding process. Appropriate clean policy and procedure followed.	○	○	○	
62.	Scales, balances, or other equipment used for measurement is validated and calibrated at least annually.	○	○	○	
63.	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					
64.	Is the finished preparation checked to ensure it appears as expected in the master formulation record.	○	○	○	
65.	Final completed preparations assessed for weigh, mixing, clarity, odor, consistency, pH, and strength. This is documented.	○	○	○	
66.	There are established written processes that describe test or examinations conducted on the compounded preparation to ensure uniformity and integrity.	○	○	○	
67.	Labels on immediate patient specific containers include in addition to all legally required elements, identifiers for the person preparing the compound and preforming the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packing and labeling of hazardous materials.	○	○	○	
68.	Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD.	○	○	○	
69.	Labels on batch preparations include the name and quantity of all contents, date and time of preparations, preparer and verifying RPh., stability BUD, and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.	○	○	○	
70.	Preparations are stored properly prior to dispensing based upon conditions which BUD was assigned.	○	○	○	
71.	Preparations are examined immediate after preparation and again immediately prior to dispensing for any signs of instability.	○	○	○	

		Compliant			
#		Yes	No	N/A	Comments
Quality Assurance					
72.	Does pharmacy have/keep quality related event reports for compounded products.	○	○	○	

		Compliant			
#	Requirement	Yes	No	N/A	Comments
Quality Assurance					
73.	Does the facility QA program identify action limits or thresholds and the appropriate follow up mechanism when action limits or thresholds are	○	○	○	
74.	Does the pharmacy have a recall system in place to communicate with the patients and physicians regarding affected compounded products.	○	○	○	

Notes

Notes

Inspector Signature: Sandra Burns Knuckles 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 : _____