South Carolina Department of Labor, Licensing and Regulation
P.O. Box 11927
Columbia, SC 29211
803-896-4700 FAX: 803-896-4596

S.C. Board of Pharmacy Permit Inspection Report

Permit Name: _____

Permit Number: _____ **Date:** _____

DBA: _____

Address: _____ **City:** _____

State: _____ **Zip:** _____ **County:** _____

Pharmacist: _____ **Pharmacist License #:** _____

Consultant: _____ **Consultant License #:** _____

Permit Holder: _____ **Phone:** _____

Inspection Type:
☐ New ☐ Follow up ☐ Routine ☐ Relocation ☐ Consultation
☐ Change of Ownership ☐ Change of Name ☐ Change of Location

Type of Permit:

☐ Institutional Pharmacy	☐ Non Sterile Compounding	☐ Medical Gas/DME
☐ Narcotic Treatment Program Permit	☐ Non Dispensing Drug Outlet	☐ Retail Pharmacy
☐ Narcotic Treatment Prg. Satellite Permit	☐ Nuclear Pharmacy	☒ Sterile Compounding
☐ Wholesale Distributor Drug Outlet	☐ Central Fill Inspection	☐ Consultation
☐ Federally Qualified Health Clinic	☐ Third Party Logistics	☐ 503B Outsourcing
☐ EMS Non-Dispensing Drug Outlet Facility	☐ Manufacturer/Repackager	

General Business Description:

Type Sterile Compounding

S	U	N/A	Statute Inspection Items	Comment
			40-43-88(F) - Standard operating procedures that address the operations of the sterile compounding process are present, updated, and in use	
			40-43-88(B),(C) - Facility design, equipment and devices are appropriate for risk level of CSPs prepared by the facility, and compounding areas must be segregated	
			40-43-88(C)(8) - Compounding area(s) allow for visual observation	
			40-43-88(B)(2)(b),(C)(2)(c) - Compounding area(s) are not be a thruway for traffic	
			40-43-88(C)(2)(e),(f) - Compounding area(s) are segregated and have walls, floor, ceiling and work surfaces constructed of materials that are nonporous and do not produce particulate matter	

S - satisfactory U - unsatisfactory (results in a violation) N/A- Not Applicable

S	U	N/A	Statute Inspection Items	Comment
			40-43-88(B),(C) - Compounding area(s) are ventilated in a manner that does not interfere with the outward flow of air from the hood	
			40-43-88(C)(6) - Compounding area(s) are not used for unpacking bulk supplies	
			40-43-88(C)(9) - Compounding area(s) are not used for storage of bulk supplies and materials	
			40-43-88(C)(11) - Compounding area(s) have an eyewash station and sink with hot and cold running water readily accessible to the area(s)	
			40-43-88(D)(7) - An appropriate facility-specific environmental sampling procedure is followed for airborne viable particles based on a risk level assessment of compounding activities performed	
			40-43-88(D)(7)(b) - Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments, including LAFWs, CAIs, clean room or buffer areas, and ante areas, is performed by properly trained individuals for all compounding risk levels (Impaction is the preferred method of volumetric air sampling)	
			40-43-88(D)(7)(c) - For all compounding risk levels, air sampling is be performed at locations prone to contamination during compounding activities and during other activities (e.g. staging, labeling, gowning, and cleaning), including zones of turbulence within LAFW and other areas where air turbulence may enter the compounding area	

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S	U	N/A	Statute Inspection Items	Comment
			40-43-88(D)(7)(d) - Corrective actions are taken when CFU counts for each ISO classification are exceeded or when microorganisms are identified that are potentially harmful to patients receiving CSPs	
			40-43-88(D)(2)-(4) - Clean room and hood are certified every six (6) months	
			40-43-88(D)(5) - Documentation of pre-filter changes is maintained	
			40-43-86(CC)(5)(b) - Equipment used in compounding is routinely inspected and calibrated	
			40-43-88(E)(1)-(8) - Hazardous medications compounded in appropriate areas	
			40-43-88(C)(10) - Logs are maintained for proper temperature and humidity range of storage areas	
			40-43-88(F)(3) - Logs are maintained for cleaning and disinfecting of the sterile compounding areas and devices	
			40-43-88(D)(6)(c) - Logs for pressure differential are maintained	
			40-43-86(CC)(3) - Training (and/or continuing education) of compounding personnel in compounding of sterile preparations is documented	
			40-43-88(E)(8) - Training (and/or continuing education) of compounding personnel in compounding, handling, and disposal of hazardous agents is documented	

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			40-43-88(F) - Personnel are familiar with facility's standard operating procedures	
			40-43-86(CC)(3)(c); 40-43-88(F)(1) - Personnel understand and use appropriate outer and over wear items	
			40-43-86(A)(16)(j) - Personnel thoroughly cleanse their fingernails and wash their hands	
			40-43-86(CC)(3) - Personnel free from apparent illness or open lesions	
			40-43-88(D)(1) - Aseptic manipulations are properly executed	
			40-43-86(CC)(3)(c) - Protective apparel is worn by personnel compounding cytotoxic agents	
			40-43-88(G)(1) - No food or drinks are introduced into ante-areas, buffer areas, or segregated compounding areas	
			40-43-86(CC)(6) - Adequate formulas and logs are maintained	
			40-43-86(I)(1)(b) - Adequate compounding logs are maintained for repackaged sterile preparations	
			40-43-88(B) - Compounded sterile preparations are stored according to guidelines	
			40-43-88(B) - BUDs are assigned according to risk level of CSP	
			40-43-88(B)(4) - Preparations compounded from non-sterile ingredients are appropriately sterilized	
			40-43-88(H) - Adequate reference materials are present for stability, compatibility, storage and beyond use dates	
			40-43-88(I) - Preparations are labeled properly	

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S	U	N/A	Statute Inspection Items	Comment
			40-43-88(J) - Bulk or unformulated drug substances and added substances or excipients are stored in tightly closed containers under temperature, humidity, and lighting conditions that are either indicated in official monographs or approved by suppliers, and the date of receipt is clearly and indelibly marked on each package of ingredients	
			40-43-86(CC)(2)(c) - Pharmacists ensure drug substances for compounding that are received, stored, or used meet official compendia requirements or the accepted standard of the practice of pharmacy	
			40-43-86(CC)(6)(c) - All components, additive and non-additive, are checked by a pharmacist before dispensing	
			40-43-88(F)(1) - Policy/procedure requiring annual training and evaluation of sterile compounding personnel is present, updated, and used	
			40-43-88(F)(2) - Policy/procedure requiring semi-annual media fill test representative of high risk compounding for all personnel authorized is present, updated, and used	
			40-43-88(F)(3) - Policy/procedure for cleaning and disinfecting of the sterile compounding areas and devices is present, updated, and used	
			40-43-88(F)(4) - Policy/procedure to ensure identity, quality, and purity of ingredients is present, updated, and used	
			40-43-88(F)(5) - Policy/procedure for sterilization methods for high risk CSPs is present, updated, and used	
			40-43-88(F)(6) - Policy/procedure for establishment of appropriate storage requirements and BUDs is present, updated, and used	

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S	U	N/A	Statute Inspection Items	Comment
			40-43-88(F)(7) - Policy/procedure for measuring, mixing, dilution, purification, packaging, and labeling is present, updated, and used	
			40-43-88(F)(8) - Policy/procedure for unpacking and introducing supplies into the sterile compounding environment is present, updated, and used	
			40-43-88(F)(9) - Policy/procedure for compounding activities that require the manipulation and disposal of a hazardous material is present, updated, and used	
			40-43-88(F)(10) - Policy/procedure for expiration dating of single dose and multiple dose containers is present, updated, and used	
			40-43-88(F)(11) - Policy/procedure for quality control and quality assurance of CSP processes is present, updated, and used	
			40-43-88(F)(12) - Policy/procedure for accessing and reviewing material safety data sheets is present, updated, and used	
			40-43-88(F)(13) - Policy/procedure for use of investigational drugs is present, updated, and used	
			40-43-88(F)(14) - Written policy/procedure for required equipment and controlled procedures for use is present, updated, and used	
			40-43-88(F)(15) - Policies/procedures for patient training and competency in managing therapy in the home are present, updated, and used	
			40-43-88(F)(16) - Policy/procedure for safety measures to ensure accuracy of CSPs is present, updated, and used	

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S	U	N/A	Statute Inspection Items	Comment
			40-43-88(F)(17) - Policy/procedure for maintaining compounding logs for non-patient-specific CSPs is present, updated, and used	
			40-43-86(B)(4) - The pharmacist-in-charge is assisted by a sufficient number of licensed pharmacists and registered pharmacy technicians as may be required to competently and safely provide pharmacy services	

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This inspection report describes alleged violations of the Pharmacy Practice Act. All violations and matters needing improvement must be corrected.

You must notify the Board in writing or e-mail of those corrections within _____ days.

Failure to comply with these terms may result in Board action.
This inspection report has been reviewed with me, and I have been advised as to my responsibilities under the Pharmacy Practice Act.

Contact Name

_____

Inspector Signature **Contact Title** **Licensed Pharmacist/Designee Signature**

_____

Inspector's Name **Contact License**

_____ _____

Inspector's Email **Contact Email(s)**

_____ _____