South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy

PO Box 11927, Columbia, SC 29211

Inspection Report – Sterile Compounding Pharmacy

Permit Name: _____ Permit Number: _____

S-Satisfactory I-Improvement Needed U-Unsatisfactory N/A – Not Applicable

Reference	Description	S	I	U	N/A
	Facility:				
40-43-88(B)	Pharmacy has separate area designated for placement of Class 100 laminar airflow hood, which must: (1) Allow visual observation (2) Not be a thruway for traffic (3) Have walls, floor, ceiling, and work surfaces constructed of materials that are nonporous and do not produce particulate matter (4) Be ventilated in a manner that will not interfere with the outward flow of air from the hood (5) Not be used for unpacking bulk supplies (6) Not be used for storage of bulk supplies and materials (7) Have an eye wash station and sink readily accessible to the area.				
40-43-86(CC)(4)	Bulk medications and other chemicals or materials used in the compounding of medication must be stored in adequately labeled containers in a clean, dry, and temperature-controlled area or, if required, under refrigeration.				
40-43-88(C)(9)	A sink with hot and cold running water readily accessible to the sterile products preparation area with immediate availability of germicidal skin cleanser and either a warm air blower or non-shedding single-use towels for hand drying must be available to all personnel preparing sterile pharmaceuticals.				
40-43-88(C)(5)	Documentation of pre-filter changes in accordance with manufacturer's specifications.				
40-43-86(CC)(5)	Equipment used in compounding is routinely inspected, calibrated, if necessary, or checked to ensure proper performance.				
40-43-88(C)(3)	Airflow Hood Certified every 12 months and certification documents retained for 2 years.				
40-43-88(I)(8)	Class II safety cabinets certified every 12 months.				
40-43-88 (I)(1)	Hazardous medications compounded in appropriate area.				
40-43-86(A)(10)	Storage areas (pharmacy, refrigerator, freezer, and compounding area) maintained at proper temperature.				
40-43-88(C)(2)	Logs maintained for cleaning of airflow hood work surfaces with seventy percent isopropyl alcohol or an equivalent disinfectant every eight-hour work shift and as needed for microbial, drug, and particulate matter removal. This cleaning must be documented by date, time, and initials. Documentation must be retained for 2 years.				
40-43-88(C)(4)	Logs maintained for cleaning of sterile compounding area. Cleaning and disinfection occurs at least weekly with appropriate agents according to written policy and procedures. Documentation must include date and initials and retained for 2 years.				

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	Personnel:	S	I	U	N/A
40-43-86(CC)(3)	Training and/or continuing education in compounding of sterile products is documented.				
40-43-88(I)(6)	Annual training in hazardous materials handling and precautions is documented.				
40-43-88(I)(7)	Annual documentation indicating personnel have been informed of the carcinogenic, mutagenic, and teratogenic nature of the cytotoxic agents handled.				
40-43-86(A)(16)(j)	Personnel, before compounding prescriptions, shall thoroughly cleanse their fingernails and wash their hands.				
40-43-86(CC)(3)	Personnel use appropriate protective apparel (ie. gown, sterile gloves, face mask, bouffant cover, beard cover).				
40-43-86(CC)(3)	Personnel with direct contact with components, medication containers, closures, in-process materials, and medication products shall be free from apparent illness or open lesions that may adversely affect the safety or quality of a compounded drug product.				
40-43-88(D)(1)	Aseptic manipulations are properly and promptly executed.				
40-43-88(D)(2)	Closed system transfers must be used in compounding sterile pharmaceuticals, except for initial withdrawals from ampules.				
40-43-88(I)(2)	Protective apparel must be worn by personnel compounding cytotoxic agents including gloves, closed front gowns with tight cuffs and masks.				
	Products:				
40-43-86(CC)(6)	Adequate formulas and logs maintained for non-sterile to sterile compounded products.				
40-43-86(I)(1)(b)	Adequate compounding logs maintained for repackaged sterile products (excluding patient-specific medications prepared in accordance with manufacturers' instructions).				
40-43-88(D)(3)	Compounded Sterile Products stored according to guidelines.				
40-43-88 (F)(10)	Expiration Date/Beyond use dates are assigned according to stability and sterility of the compounded product or research-supported standard of practice.				
40-43-86(CC)(7)	Excess compounded product is labeled and contains estimated beyond use date based on pharmacist's professional judgment, appropriate testing, or published data.				
40-43-88(D)(5)	Products prepared from non-sterile ingredients appropriately sterilized.				
40-43-88(E)	At least one current reference material present for stability and compatibility, of sterile pharmaceuticals.				

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Reference	Description	S	I	U	N/A
40-43-88(F)	Products labeled properly				
40-43-86(CC)(2)(c)	Pharmacists shall receive, store, or use drug substances for compounding that meet official compendia requirements or the accepted standard of the practice of pharmacy.				
40-43-88(C)(7)	All solutions, additive and non-additive, must be checked by a pharmacist before dispensing. The checking pharmacist's initials must appear on either the prescription or medical order, the patient's profile, a compounding record, or label. Only one system must be used. Initials may be computer produced or stamped for solutions containing non-controlled additives.				
	Policies and Procedures:				
40-43-88(K)	Standard Operating Procedures which address the operations of the sterile compounding process present, updated and in use. The manual shall include policies and procedures as applicable for the following: (1) Quality control (2) Sterile technique (3) Destruction of returned solutions (4) Labeling of injectable solutions (5) Drug recall procedures (6) Investigational drugs (7) Handling and disposal of hazardous waste (8) Cytotoxic agents (9) Maintenance of patient profiles (10) Material safety data sheets				
40-43-88(I)(2)	Written procedures for handling spills of cytotoxic agents must be developed**.**				