Inspection Report – Sterile Compounding Pharmacy

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-(F)	Standard Operating Procedures which addresses the operations of the sterile compounding process present, updated and in use				
40-43-88(B) 40-43-88(C)	Facility design, equipment and devices are appropriate for risk level of CSPs prepared by facility. Areas must be segregated and: 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 eyewash station and sink with hot and cold running water readily accessible to the area. Germicidal skin cleanser and warm air blower or non-shedding single-use towels for hand drying must be available to all personnel preparing sterile pharmaceuticals				
40-43-88(D)(7)(a-d)	An appropriate facility-specific environmental sampling procedure must be followed for airborne viable particles based on a risk level assessment of compounding activities performed: 1. The documentation must include sample location, method of collection, volume of air sampled, time of day, and action levels 2. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments, including LAFWs, CAIs, clean room or buffer areas, and ante areas must be performed by properly trained individuals for all compounding risk levels. Impaction is the preferred method of volumetric air sampling 3. For all compounding risk levels, air sampling must be performed at locations prone to contamination during compounding activities and during other activities such as staging, labeling, gowning and cleaning. Locations must include zones of turbulence within LAFW and other areas where air turbulence may enter the compounding area 4. Corrective actions must be taken when CFU counts for each ISO classification are exceeded, or when microorganisms are identified that are potentially harmful to patients receiving CSPs				

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40-43-88(D)(2)(3)(4)	Clean Room and Hood Certified every 6 months and when relocated Environmental Air Sampling every 6 months				
40-43-88 (D)(5)	Documentation of pre-filter changes in accordance with the manufacturer's specification				
40-43-86(CC)(5)	Equipment used in compounding is routinely inspected, calibrated, if necessary or checked to ensure proper performance				
40-43-88(E)	Hazardous medications compounded in appropriate area				
40-43-88(C)(10)	Logs maintained for proper temperature and humidity monitoring of drug storage and compounding areas. Logs maintained for proper temperature of drug refrigerators and freezers.				
40-43-88(F)(3)	Logs maintained for cleaning and disinfecting of the sterile compounding areas and devices with appropriate documentation				
40-43-88(D)(6)(c)	Logs for pressure differential maintained if applicable				
	Personnel:				
40-43-86(CC)(3)	Training and/or continuing education in compounding of sterile preparations is documented				
40-43-88(E)(8)	Training in hazardous materials handling and precautions is documented				
40-43-88(F)	Personnel are familiar with facility's Standard Operating Procedures				
40-43-86(CC)(3); 40-43-88(F)(1)	Personnel understands and uses appropriate outer and over-wear items (gowning, gloving, and related supplies)				
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 with direct contact with components, medication containers, closures, in-process materials, and medication preparations shall be free from apparent illness or open lesions that may adversely affect the safety or quality of a compounded drug preparation				
40-43-88(D)(1)	Aseptic manipulations are properly executed				
40-43-86(CC)(3)	Protective apparel must be worn by personnel compounding cytotoxic agents including gloves, closed front gowns with tight cuffs and masks.				
40-43-88(G)(1)	No food or drinks introduced into ante-areas, buffer areas, or segregated compounding areas				
	Preparations:				
40-43-86(CC)(6)	Adequate formulas and logs maintained for non-sterile to sterile preparations				
40-43-86(I)(1)(b)	Adequate compounding logs maintained for repackaged sterile preparations (excluding patient-specific medications prepared in accordance with manufacturers' instructions)				
40-43-88(B)	Compounded Sterile Preparations stored according to guidelines				
40-43-88(B)	BUDs are assigned according to Risk Level of CSP or as verified by sterility test or process validation				

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40-43-88(B)(4)	Preparations compounded from non-sterile ingredients appropriately sterilized				
40-43-88(H)	Adequate reference materials present for stability, compatibility, storage and beyond use dates				
40-43-88(I)	Preparations labeled properly				
40-43-88(J)(1)	Bulk or unformulated drug substances and added substances or excipients stored properly and labeled with date of receipt.				
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 components, 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 mat be computer produced or stamped for preparations containing non-controlled additives.				
	Policies and Procedures:				
40-43-88(F)(1)	Annual Training and evaluation of sterile compounding personnel				
40-43-88(F)(1)(a)	Semi-annual media fill test representative of high risk compounding for all personnel authorized to prepare high risk CSPs				
40-43-88(F)(3)	Cleaning and disinfecting of the sterile compounding areas and devices with appropriate documentation				
40-43-88(F)(4)	Process to ensure identity, quality and purity of ingredients				
40-43-88(F)(5)	Sterilization methods for High Risk CSPs				
40-43-88(F)(6)	Establishment of appropriate storage requirements and BUDs				
40-43-88(F)(7)	Measuring, mixing, dilution, purification, packaging and labeling				
40-43-88(F)(8)	Unpacking and introducing supplies into the sterile compounding environment				
40-43-88(F)(9)	Compounding activities that require the manipulation and disposal of a hazardous material				
40-43-88(F)(10)	Expiration dating of single dose and multiple dose containers				
40-43-88(F)(11)	Quality Control and Quality Assurance of CSP processes				
40-43-88(F)(12)	Material Safety Data Sheets				
40-43-88(F)(13)	Use of Investigational Drugs				
40-43-88(F)(14)	Written procedures for required equipment calibration, maintenance, monitoring for proper function and controlled procedures for use of equipment and specified time frames				
40-43-88(F)(15)	Patient training and competency in managing therapy in the home environment, if applicable				
40-43-88(F)(16)	Safety Measures to ensure accuracy of CSPs				
40-43-88(F)(17)	Compounding Logs for non-patient specific CSPs				