

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
	<b>Facility Accredited:</b>				
40-43-88-K P&P 137	Standard Operating Procedures which addresses the operations of the sterile compounding process present, updated and in use				
	<b>Facility:</b>				
40-43-88(B)	Adequate area for preparation of sterile products				
40-43-88(C)	Policies and procedures address cleaning and maintenance of facility				
40-43-88(B)(I)	ISO Classification sufficient for risk level of products compounded				
USP 797	Clean Room and Hoods Certified every 6 months				
40-43-86(A)(10)	Maintain storage areas (pharmacy, refrigerator, freezer, and compounding area) at proper temperature				
40-43-88(C)(4)	Logs for cleaning of sterile compounding area				
P&P 132/USP 797	Logs for environmental testing of sterile compounding area				
40-43-86(CC)(5)	Adequate equipment and devices in use for the level of compounding performed. Calibration/Verification logs in place for equipment.				
	<b>Personnel:</b>				
40-43-86(CC)(3)	Evidence of training and/or continuing education in compounding of sterile products annually				
USP 797	Logs for personnel for media fill sufficient for risk level of compounded products				
40-43-88(I)(6)(7)	Personnel trained in hazardous materials handling and precautions				
40-43-88(K)	Personnel familiar with facility's Standard Operating Procedures				
40-43-86(CC)(3)	Personnel understands and uses appropriate outer and over-wear items (gowning, gloving, and related supplies)				
	<b>Products:</b>				
40-43-86(CC)(6)	Adequate formulas and logs maintained for non-sterile to sterile products				
40-43-86(I) (1b)	Adequate compounding logs maintained for repackaged sterile products (excluding patient-specific medications prepared in accordance with manufacturers' instructions)				
40-43-86(CC)(6)	Policies and procedures present which address facilities' product testing and validation				
P&P 132/137	Logs for in-house testing of products				
P&P 132/137	Logs for testing of products by outside organization				
P&P 132/137	Logs for testing for pyrogens, sterility, and potency				
40-43-88(E)	Adequate reference materials present for stability, compatibility, storage and beyond use dates				
40-43-88 (F)	Products labeled properly				
40-43-88 (H)	Patient profile or medical record maintained				
40-43-88(O)	Facility maintains a quality assurance program which is reviewed and updated annually				
40-43-88(O)	Policies and procedures in place to address patient monitoring and adverse events				