

Compounding Supplemental

Pharmacy License # _____

Type of compounding performed

Simple _____ Moderate _____ Complex _____ Hazardous _____

Compounding During Inspection? Yes _____ No _____

Distribution of non-patient specific compounds? Yes _____ No _____

RULE	PHARMACY AREA STANDARDS	C	NC	NA
239	Commercially available products only compounded according to Rule 239.04.b			
239	FDA list is monitored.			
239.02.a	All active pharmaceutical ingredients must be obtained from an FDA registered manufacturer.			
239.02.b	Certificate of Analysis.			
239.02.c	Appropriate equipment and utensils are available, clean, and in good working order.			
239.03	Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has withdrawn or removed from the market for safety or efficacy reasons is prohibited.			
	Master Formulation Record and the Compounding Record has been reviewed.			
POLICIES AND PROCEDURES				
239.05.a.i	Appropriate training, packaging, handling, transport, and storage requirements.			
239.05.a.ii	Accuracy and precision of calculations, measurements, and weighing.			
239.05.a.iii	Determining ingredient identity, quality, and purity;			
239.05.a.iv	Labeling accuracy and completeness;			
239.05.a.v	Beyond use dating;			
239.05.a.vi	Auditing for deficiencies.			
239.05.a.vii	Maintaining environmental quality control.			
239.05.a.viii	Safe limits and ranges.			
	The non-sterile compounding area is a controlled environment and separate from the general pharmacy.			
DISTRIBUTION				
615.01.c.v.1	The compounded product is not sterile and not intended to be sterile.			
615.01.c.v.2	The compounded drug product is not further dispensed or distributed by the practitioner;			
615.01.c.v.3	The QTY of compounded drug product distributed is limited to five percent (5%) of the total number of compounded drug products dispensed and distributed on an annual basis.			
615.05	Office use compound using any controlled substances. Yes=reporting.			

RULE	Hazardous Compounding	C	NC	NA
241.01	Storage and compounding areas have sufficient general exhaust ventilation.			
241.02	Utilize a ventilated cabinet designed to reduce worker exposures.			
241.02.a	Sterile hazardous drugs must be prepared in a dedicated Class II biological safety cabinet or a barrier isolator of appropriate design.			
241.02.b	If asepsis is not required, a Class I BSC, powder containment hood or an isolator intended.			
241.03	Clearly identified storage areas, containers, prepared doses.			
241.05	Protective equipment and supplies, including spill kit.			
	Personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs.			
LABELING OF DISTRIBUTED COMPOUNDED DRUG PRODUCT				
144	Compounded and sterile prepackaged drug product distributed in the absence of a patient specific prescription.			
144	01. Drug Name. The name of each drug included 02. Strength or Concentration. The strength or concentration of each drug 03. Base or Diluents. If a sterile, the name and concentration of the base or diluents. 04. Administration. the dosage form or route of administration 05. Quantity. 06 The expiration or beyond use date. 07. Compounder Identifier. The initials or unique identifier 08. Resale. If: *A pharmacy "not for further dispensing or distribution" *An outsourcing facility "not for resale."			

C=COMPLIANT NC=NOT COMPLIANT NA=NOT APPLICABLE

Board Compliance Officer	Pharmacist Signature	Date
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