STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

Standards of Practice for Compounding Sterile Preparations (CSPs)

Florida HEALTH

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ROUTINE ☐ CHANGE LOC ☐ NEW ☐ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

File # _____

Insp # _____

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS		TELEPHONE #	EXT.	
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #

COMPOUNDING PERSONNEL	MEDIA FILLED TEST DATE	COMPOUNDING PERSONNEL	MEDIA FILLED TEST DATE

	SATISFACTORY	N/A	YES	NO
High-Risk Level CSPs				
1	Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified in rule. [64B16-27.797(1)(i)4.]	☐	☐	☐
2	Personnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannually). [64B16-27.797(1)(i),F.A.C.]	☐	☐	☐
3	High risk sterile compounded preparations greater than 25 units have antimicrobial testing prior to dispensing [64B16-27.797(7)(a)3., F.A.C.]	☐	☐	☐
Medium and Low-Risk Level CSPs				
4	Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified in rule. [64B16-27.797(1)(n)4.; (o)4.]	☐	☐	☐
5	Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 months. [64B16-27.797(1)(n), F.A.C.]	☐	☐	☐
Barrier Isolator or Compounding Environment				
6	All sterile compounds prepared in barrier isolator which has been certified as ISO 5 by independent contractor. [64B16-27.797(5)(e), F.A.C.]	☐	☐	☐
7	Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for medium and low-risk.	☐	☐	☐
	a) Anteroom/Ante area maintained within ISO class 8 [64B16-27.797(1)(a), F.A.C.]	☐	☐	☐
	b) Buffer area (clean room) maintained within ISO class 7 (separate room required for high-risk) [64B16-27.797(1)(f); (5)(a), F.A.C.]	☐	☐	☐
	c) Laminar Air Flow Hood(s) or class100 ISO room maintained within ISO class 5 [64B16-27.797(1)(k), F.A.C.]	☐	☐	☐
8	Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.]	☐	☐	☐
Antineoplastic Drugs (Cytotoxins)				
9	Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.]	☐	☐	☐
10	All cytotoxic preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F.A.C.]	☐	☐	☐
11	Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.]	☐	☐	☐
General Requirements				
12	P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16.27-797(4), F.A.C.]	☐	☐	☐
13	P & P includes verification of compounding accuracy and sterility. [64B16-27.797(4), F.A.C.]	☐	☐	☐
14	P & P includes personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.]	☐	☐	☐
15	P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.]	☐	☐	☐
16	Current reference material, hard copy or readily available online, are maintained. [64B16-27.797(5)(d), F.A.C.]	☐	☐	☐
17	Appropriate disposal containers. [64B16-27.797(5), F.A.C.]	☐	☐	☐
18	Appropriate temperature and transport devices. [64B16-27.797(5), F.A.C.]	☐	☐	☐
19	Adequate supplies (gloves, mask, etc.) to preserve a suitable environment for aseptic preparation and protective apparel for cytotoxins. [64B16-27.797(5)(6), F.A.C.]	☐	☐	☐
20	Documented on-going quality assurance program with audits at regular planned intervals. [64B16-27.797(7), F.A.C.]	☐	☐	☐
21	Compounding personnel skilled and trained based on observation. [64B16-27.797(7), F.A.C]	☐	☐	☐
22	Compounding records properly maintained [64B16-28.140(4), F.A.C.]	☐	☐	☐
23	Quantity of compounded drug is reasonable considering the intended use and nature of the practitioner's practice [64B16-27.700(3)(b), F.A.C.]	☐	☐	☐

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT _____

ID _____

Institutional Representative _____ Date _____ Investigator/Sr. Pharmacist Signature _____

Complete Save