

Insn #

STATE OF FLORIDA DEPARTMENT OF HEALTH INVESTIGATIVE SERVICES



Standards of Practice for Compounding Sterile Preparations (CSPs)

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

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

DOING BUSINESS AS DEA NUMBER PRESCRIPT STREET ADDRESS TELEPHONE # EXT. PRESCRIPT CITY COUNTY STATE/ZIP PRESCRIPT COMPOUNDING PERSONNEL MEDIA FILLED TEST DATE COMPOUNDING PERSONNEL PRESCRIPT High-Risk Level CSPs 1 Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specife4816-27.797(1)(i)(i).] 2 2 Personnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannu: 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-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified [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 mont 8 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 a) Antercom/Ante area maintained within ISO class 8 [64B16-27.797(1)(k), F.A.C.]	SPECTION ON DEPARTMENT MANAGE	R					
STREET ADDRESS TELEPHONE # EXT. CITY COUNTY STATE/ZIP PRESCRIPT COMPOUNDING PERSONNEL MEDIA FILLED TEST DATE COMPOUNDING PERSONNEL PRESCRIPT High-Risk Level CSPs Extractional set of the preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified 16:27.797(1)(0).4] Presonnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannu 3 High risk sterile compounded preparations greater than 25 units have antimicrobial testing prior to dispensing (54B16-27.797(7)(a)3., F.A.C.] Medium and Low-Risk Level CSPs Medium-risk endow-risk tyreparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified (54B16-27.797(1)(n).4; (o)A.] 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 mont Barrier Isolator or Compounding Environment Barrier Isolator or Compounding Environment 64B16-27.797(1)(n), F.A.C.] Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for a) Anteroom/Ante area maintained within ISO class 3 (64B16-27.797(1)(n), F.A.C.] b) Buffer area (clean room maintained within ISO class 1 (balacter com required for high-risk) [64B16-27.797(1)(n); (5)(a), F.A.C.]	ON DEPARTMENT MANAGE	R	DATE OF INSPECTION				
CITY COUNTY STATE/ZIP PRESCRIPT COMPOUNDING PERSONNEL MEDIA FILLED TEST DATE COMPOUNDING PERSONNEL High-Risk Level CSPs I Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified 16-27.797(1)(0.4.] 2 Personnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannuu 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 Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified [64B16-27.797(1)(n).4.; (o)A.] 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 mont 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(1)(6), F.A.C.] 7 Compounding Environment 6 All sterile compounds prepared in barrier isolator which has been certified as ISO 5 by independent contractor. [64B16-27.797(1)(6), F.A.C.] 9 Buffer area does not contain sinks and drains. [64B16-27.797(1)(6), F.A.C.] 10 bluffer area does no							
COMPOUNDING PERSONNEL MEDIA FILLED TEST DATE COMPOUNDING PERSONNEL High-Risk Level CSPs Image: Compound in the problem of							
High-Risk Level CSPs 1 Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods speci [64B16-27.797(1)(0)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 (semiannuu 3 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 [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 mont 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(1)(e), F.A.C.] 7 Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for e) Laminar Air Flow Hood(s) or class 10 ISO class 8 [64B16-27.797(1)(e), F.A.C.] 8 Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.] 9 Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.] 10 All crytotoxins) 9 Spill kits for an	PRESCRIPTION DEPARTMENT MANAGER LICENSE #				#		
 Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified [64B16-27.797(1)(i)4.] Personnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannual 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 Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified [64B16-27.797(1)(n)4.; (o)4.] Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 mont Barrier Isolator or Compounding Environment 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.] Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for 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.] Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.] Milteroplastic Drugs (Cytotoxins) Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.] All cytotoxi preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F.A.C.] P & P includes use of single/multidose containers not to exceed 797 guideli	MEDIA FILLED TEST	Γ DAT	E		_		
 Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified [64B16-27.797(1)(i)4.] Personnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannual 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 Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified [64B16-27.797(1)(n)4.; (o)4.] Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 mont Barrier Isolator or Compounding Environment 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.] Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for 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.] Buffer area does not contain sinks and drains. [64B16-27.797(5), F.A.C.] All iterile or antineoplastic agent spills. [64B16-27.797(5), F.A.C.] All cytotoxins preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F.A.C.] P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.] <							
 Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified [64B16-27.797(1)(i)4.] Personnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannual 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 Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified [64B16-27.797(1)(n)4.; (o)4.] Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 mont Barrier Isolator or Compounding Environment 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.] Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for 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.] Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.] Milteroplastic Drugs (Cytotoxins) Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.] All cytotoxi preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F.A.C.] P & P includes use of single/multidose containers not to exceed 797 guideli		-					
 Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified [64B16-27.797(1)(i)4.] Personnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannual 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 Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified [64B16-27.797(1)(n)4.; (o)4.] Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 mont Barrier Isolator or Compounding Environment 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.] Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for 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.] Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.] Milteroplastic Drugs (Cytotoxins) Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.] All cytotoxi preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F.A.C.] P & P includes use of single/multidose containers not to exceed 797 guideli	SATISFACTORY	N/A	YF	ES	NO		
 Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified [64B16-27.797(1)(i)4.] Personnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannual 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 Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified [64B16-27.797(1)(n)4.; (o)4.] Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 mont Barrier Isolator or Compounding Environment 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.] Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for 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.] Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.] Milteroplastic Drugs (Cytotoxins) Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.] All cytotoxi preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F.A.C.] P & P includes use of single/multidose containers not to exceed 797 guideli							
 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 Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified [64B16-27.797(1)(n)4.; (o)4.] Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 mont Barrier Isolator or Compounding Environment 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.] Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for a) Anteroom/Ante area maintained within ISO class 7 (separate room required for high-risk) [64B16-27.797(1)(f); (5)(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.] Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.] Antineoplastic Drugs (Cytotxins) Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.] 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.] P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.] P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.] P & P includes verification of compounding accuracy and sterility. [64B16-27.797(4), F.A.C.] P & P includes verification of compounding accuracy and s	ed in rule.						
 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 Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified [64B16-27.797(1)(n)4.; (o)4.] Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 mont Barrier Isolator or Compounding Environment 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.] Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for a) Anteroom/Ante area maintained within ISO class 7 (separate room required for high-risk) [64B16-27.797(1)(f); (5)(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.] Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.] Antineoplastic Drugs (Cytotxins) Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.] 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.] P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.] P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.] P & P includes verification of compounding accuracy and sterility. [64B16-27.797(4), F.A.C.] P & P includes verification of compounding accuracy and s	High-Risk Level CSPs I 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.] 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.] Redium and Low-Risk Level CSPs Medium and Low-Risk Level CSPs 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.] 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.] [64B16-27.797(1)(n)4.; (o)4.] 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.] [64B16-27.797(1)(n), F.A.C.] Barrier Isolator or Compounding Environment [64B16-27.797(5)(e), F.A.C.] [64B16-27.797(5)(e), F.A.C.] 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.] [64B16-27.797(5)(e), F.A.C.] All sterile 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.]						
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 [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 mont 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 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 waste meets all applicable requirements. [64B16-27.797(4), 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.] 12 P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.] 12		-		╺┥┾	┍━┽┦		
 Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified [64B16-27.797(1)(n)4.; (o)4.] Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 mont Barrier Isolator or Compounding Environment 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.] Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for 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.] Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.] Antineoplastic Drugs (Cytotoxins) Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.] All cytotxic preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F.A.C.] General Requirements P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.] P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.] P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.] P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.] P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.] Current reference material, hard copy or readily available online, are maintained. [64B16-27.797(5)(
 [64B16-27.797(1)(n)4.; (o)4.] Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 mont Barrier Isolator or Compounding Environment 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.] Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for 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.] Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.] Antineoplastic Drugs (Cytotoxins) 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.] General Requirements P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.] P & P includes use of single/multidose contain in aseptic manipulation skills. [64B16-27.797(4), F.A.C.] P & P includes neuron develuation in aseptic manipulation skills. [64B16-27.797(5)(d), F.A.C.] I P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.] I P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.] I Current reference material, hard copy or readily available online, are maintained. [64B16-27.797(5)(d), F.A.C.] 							
 Barrier Isolator or Compounding Environment 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.] Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for 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.] 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 personnel training and evaluation in aseptic manipulation skills. [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.]][
 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.] Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for 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.] 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 personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.] 14 P & P includes personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(5)(d), 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.] 	is. [64B16-27.797(1)(n), F.A.C.]						
 Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for 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.] 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 personnel training and evaluation in aseptic manipulation skills. [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.] 					لي		
 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 11 Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.] 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 personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.] 14 P & P includes environmental quality and control. [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.] 				┛┤	H		
 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 11 Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.] 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 personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.] 14 P & P includes environmental quality and control. [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.] 	r medium and low-risk.				Ľ		
 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 11 Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.] 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.] 							
 Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.] Antineoplastic Drugs (Cytotoxins) Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.] All cytotoxic preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.] General Requirements P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.] P & P includes personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.] P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.] Current reference material, hard copy or readily available online, are maintained. [64B16-27.797(5)(d), 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 11 Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.] 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.]							
 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 11 Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.] 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.] 							
 All cytotoxic preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.] General Requirements P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.] P & P includes verification of compounding accuracy and sterility. [64B16-27.797(4), F.A.C.] P & P includes personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.] P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.] Current reference material, hard copy or readily available online, are maintained. [64B16-27.797(5)(d), 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.]							
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.]	0 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.]						
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.]	11 Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), 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.]							
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.]					Ц		
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.]							
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.]		\square	┢┝┝	┛	H		
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.]			┛┤	Цľ		
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]				┛┤	\square		
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.]					\square		

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