



**STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
INVESTIGATIVE SERVICES**



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**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

File # \_\_\_\_\_  
Insp # \_\_\_\_\_

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

SATISFACTORY    N/A    YES    NO

|    |  |  |  |  |
|----|--|--|--|--|
| 1  | Types of sterile compounding prepared (or expected to prepare) per [64B16-27.797, F.A.C.]. <b>Undersigned pharmacist attests:</b>  |  |  |  |
|    | <b>a) High-Risk Level CSPs</b> (If yes, must complete items 5 & 6 - may not answer N/A)  |  |  |  |
|    | <b>b) Immediate Use CSPs</b> (If yes, must complete Items 7 & 8 - may not answer N/A)  |  |  |  |
|    | <b>c) Low-Risk Level CSPs</b> (If yes, must complete items 9 & 10 - may not answer N/A)  |  |  |  |
|    | <b>d) Medium-Risk CSPs</b>   |  |  |  |
|    | <b>e) Antineoplastic Drugs (Cytotoxins)</b> (If yes, must complete items 18, 19, 20 & 22 - may not answer N/A)   |  |  |  |
| 2  | All sterile compounds prepared in barrier isolator? If yes, may answer NA to 3b, 3c, 3d, 4, & 21. [64B16-27.797(5)(e), F.A.C.]   |  |  |  |
| 3  | Compounding environment appropriate for Risk Level (certification by independent qualified organization).  |  |  |  |
|    | <b>a) Barrier Isolator?</b>  |  |  |  |
|    | <b>b) Anteroom/Ante area?</b>  |  |  |  |
|    | <b>c) Buffer Area (Clean Room)?</b>  |  |  |  |
|    | <b>d) Laminar Air Flow Hood(s)?</b>  |  |  |  |
| 4  | Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.]  |  |  |  |
| 5  | 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), F.A.C.] |  |  |  |
| 6  | Personnel authorized to compound high-risk-level CSPs completed a media-filled test within the past 6 months (semiannually). [64B16-27.797(1)(i), F.A.C.]                                      |  |  |  |
| 7  | Preparation time does not exceed 1 hour when preparing Immediate use CSPs. [64B16-27.797(1)(j), F.A.C.]  |  |  |  |
| 8  | Preparation is properly labeled if preparer does not administer or witness administration when preparing immediate-use CSPs. [64B16-27.797(1)(j), F.A.C.]                                      |  |  |  |
| 9  | Storage recommendations in rules are not exceeded when preparing low-risk CSPs. [64B16-27.797(1)(n), F.A.C.]   |  |  |  |
| 10 | Personnel authorized to compound low-risk level CSPs completed a media-filled test within the past 12 months. [64B16-27.797(1)(n), F.A.C.]   |  |  |  |
| 11 | P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.]  |  |  |  |
| 12 | P & P includes verification of compounding accuracy and sterility. [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 | Appropriate disposal containers. [64B16-27.797(5), F.A.C.]   |  |  |  |
| 16 | Appropriate temperature and transport devices. [64B16-27.797(5), F.A.C.]   |  |  |  |
| 17 | Adequate supplies (gloves, mask, etc.) to preserve a suitable environment for aseptic preparation. [64B16-27.797(5), F.A.C.]   |  |  |  |
| 18 | Spill kits for antineoplastic agent spills if required. [64B16-27.797(5), F.A.C.]  |  |  |  |
| 19 | Current reference material (hard-copy or on-line). [64B16-27.797(5); and 64B16-27.797(1)(2), F.A.C.]   |  |  |  |
| 20 | All preparations are compounded in a vertical flow, Class II or biological safety cabinet. [64B16-27.797(6), F.A.C.]   |  |  |  |
| 21 | Protective apparel requirements are met. [64B16-27.797(6), F.A.C.]   |  |  |  |
| 22 | Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.]  |  |  |  |
| 23 | Documented on-going quality assurance. [64B16-27.797(7), F.A.C.]   |  |  |  |
| 24 | Quality assurance audits at regular planned intervals. [64B16-27.797(7), F.A.C.]   |  |  |  |
| 25 | Compounding personnel skilled and trained based on observation. [64B16-27.797(7), 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.

PRINT NAME OF RECIPIENT \_\_\_\_\_

ID \_\_\_\_\_

Institutional Representative \_\_\_\_\_  
INV 797 Created 8/11

Date \_\_\_\_\_

Investigator/Sr. Pharmacist Signature \_\_\_\_\_

Save