

West Virginia Board of Pharmacy

2310 KANAWHA BOULEVARD EAST, CHARLESTON WV 25311

INITIAL INSPECTION FOR A NEW STERILE COMPOUNDING FACILITY

THIS FORM IS TO BE COMPLETED IN CONJUNCTION WITH ANY FACILITY INSPECTION IF STERILE PERMIT IS HELD.

	24 HOUR PHONE	DATE
	BOP LICENSE #	
	COMPOUNDING SUPERVISOR OR P. I. C. IF NO SUPERVISOR	
	THEIR LICENSE #	

THIS INSPECTION IS BASED ON WV PHARMACY LEGISLATIVE RULES #15-1-15.1.2 & #15-1-16 & U S P STANDARDS CHAPTER 797. CITATIONS LISTING PAGE & COLUMN ARE FROM USP CHAPTER 797 (2012 PDF). CITATIONS LISTING NUMBERS ARE FROM PHARMACY LAWS & REGULATIONS

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|---|-------------|----------------|
| 1. IS SUFFICIENT SPACE AVAILABLE TO ALLOW EMPLOYEES TO FULFILL DUTIES SAFELY & ACCURATELY? | 15-1-16.6.1 | Y ___ N ___ |
| 2. WILL YOU PREPARE LOW ___ MEDIUM ___ AND/OR HIGH RISK ___ LEVEL CSP'S? | p.2 col.1 | |
| <u>POLICIES & PROCEDURES & DOCUMENTATION MUST ADDRESS AT LEAST THE FOLLOWING</u> | | |
| 3. CONDUCT TRAINING OF PERSONNEL IN BASIC FUNDAMENTALS OF STERILE COMPOUNDING | p.7 c.1 | Yes ___ No ___ |
| 4. CONDUCT TRAINING & OBSERVATION OF PROPER HAND HYGEINE & GARBING TECHNIQUES | p.17 c.1 | Yes ___ No ___ |
| 5. CONDUCT TRAINING & OBSERVATION OF ASEPTIC TECHNIQUE & MANIPULATION OF EQUIPMENT | p.17 c.1 | Yes ___ No ___ |
| 6. TRAINING & OBSERVATION OF MEDIA FILL TESTING TO BE DONE ANNUALLY | p.7 c.1 | Yes ___ No ___ |
| 7. TRAINING & OBSERVATION OF GLOVED FINGER TEST ANNUALLY | p.17 c.2 | Yes ___ No ___ |
| 8. WRITTEN PROCEDURES FOR CLEANING & DISINFECTION ON DAILY BASIS | p.15 c.2 | Yes ___ No ___ |
| 9. WRITTEN PROCEDURES FOR CLEANING & DISINFECTION ON MONTHLY BASIS | p.15 c.2 | Yes ___ No ___ |
| 10. WRITTEN PROCEDURES OF SPECIFIC CLEANING AGENTS TO BE USED & THEIR ROTATION | p.35 c1 | Yes ___ No ___ |
| 11. WRITTEN PROCEDURES FOR USE OF STERILE ALCOHOL FOR DISINFECTION | p.31 | Yes ___ No ___ |
| 12. CLEANING PROCEDURES INCLUDE EQUIPMENT TO BE USED & THEIR STORAGE LOCATIONS | p.15 | Yes ___ No ___ |
| 13. PEC EQUIPMENT IS CLEANED BEFORE EACH SHIFT & ROUTINELY DURING THE COMPOUNDING ACTIVITY | p.15 | Yes ___ No ___ |
| 14. CUSTODIAL STAFF IS TRAINED IN CLEANING PROCEDURES & PROPER DISPOSAL OF WASTE | p.8 c.2 | Yes ___ No ___ |
| 15. WRITTEN PROCEDURES FOR CLEAN UP OF BREAKS & SPILLS | p.8 c.1 | Yes ___ No ___ |
| 16. RECIPIES & FORMULAS ARE DOCUMENTED FOR COMMONLY PREPARED STERILE PRODUCTS | p. 22 c.1 | Yes ___ No ___ |
| 17. WORKSHEETS ARE MAINTAINED FOR EACH CSP PREPARED & ARE SIGNED BY COMPOUNDING PERSONS | p. 22 c.1 | Yes ___ No ___ |
| 18. ALL TECHNICIAN CALCULATIONS ARE CHECKED BY A PHARMACIST PRIOR TO MIXING | 15-7-5.1e | Yes ___ No ___ |
| 19. LABELING OF COMPOUNDED STERILE PRODUCTS IS DONE ACCORDING TO RULE | 15-1-22 | Yes ___ No ___ |
| 20. ALL PACKAGED & LABELED CSP'S ARE VISUALLY INSPECTED BY A PHARMACIST | 15-7-5.1e | Yes ___ No ___ |
| 21. DOCUMENTATION ON PROPER STORAGE & HANDLING OF RAW MATERIALS & COMPLETED CSP's | p.16 c.1 | Yes ___ No ___ |
| 22. THE STORAGE REQUIRMENTS & DELIVERY OF COMPLETED COMPOUNDED STERILE PRODUCTS | p.22 c.1 | Yes ___ No ___ |
| 23. OPENED OR PARTIALLY USED PACKAGES FOR LATER USE ARE PROPERLY LABELED & STORED | p.5 c1&2 | Yes ___ No ___ |
| 24. THE CRITERIA FOR DETERMINING BEYOND USE DATING (BUD) | p.22 c.1 | Yes ___ No ___ |
| 25. PROPER PROCEDURES FOR REPORTING & DOCUMENTING ADVERSE REACTIONS | p.25 c.2 | Yes ___ No ___ |
| 26. THE ANTEROOM MAINTAINS AN ISO 8 ENVIRONMENT | p.2 c.1 | Yes ___ No ___ |
| 27. THE BUFFER (CLEAN) ROOM IS MAINTAINED AT ISO 7 ENVIRONMENT | p.11 c.1 | Yes ___ No ___ |
| 28. THE ANTE ROOM IS SEPERATED FOR THE BUFFER(CLEAN) ROOM BY A LINE OF DEMARCATION | p.15 c.1 | Yes ___ No ___ |
| 29. THERE ARE NO SINKS OR DRAINS IN THE BUFFER(CLEAN) ROOM | p.12 c.2 | Yes ___ No ___ |
| 30. THE BUFFER(CLEAN) ROOM HAS HANDS FREE ACCESS | | Yes ___ No ___ |
| 31. THE PHARMACY MAINTAINS A WRITTEN QUALITY ASSURANCE PROGRAM WITH ANNUAL UPDATES | p.26 c.1 | Yes ___ No ___ |

NEW STERILE PERMIT INSPECTION-USP STANDARDS

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| 32. | BUFFER ROOM FOR COMPOUNDING MAINTAINS POSITIVE AIR PRESSURE | p.12 c.1 | Yes_____ No_____ |
| 33. | AIR SAMPLING & CERTIFICATION OF ROOM ISO STANDARDS IS DONE AT LEAST SEMI-ANNUALLY | p.14 c.2 | Yes_____ No_____ |
| 34. | SURFACE SAMPLING OF WORK AREAS WITH GROWTH MEDIUM IS DONE & CULTURED & RESULTS LOGGED | p.14 c.1 | Yes_____ No_____ |
| 35. | ALL SURFACES OF CLEAN ROOM ARE SMOOTH, SEALED & FLOOR JUNCTURES ARE COVERED | p.12 c.1 | Yes_____ No_____ |
| 369. | PLACEMENT OF PRIMARY ENGINEERING CONTROLS CONFORM TO USP 797 GUIDELINES | p.13 c.1 | Yes_____ No_____ |
| 37. | PLACEMENT OF PRIMARY ENGINEERING CONTROLS PERMIT CLEANING OF ALL SURFACES | p.13 c.1 | Yes_____ No_____ |
| 38. | REQUIREMENTS OF AIR CHANGES PER HOUR (ACPH) IN ROOMS AND PEC | p. 12 | Yes_____ No_____ |
| 39. | ADDITIONAL REQUIREMENTS FOR FACILITIES COMPOUNDING HAZARDOUS DRUGS NA_____ | | |
| 40. | UP TO DATE REFERENCE MATERIAL ON HAZARDOUS DRUGS & THEIR HANDLING & STORAGE | p. 28 | Yes_____ No_____ |
| 41. | BSC & CACI CABINETS MAINTAIN A NEGATIVE AIR PRESSURE TO CLEAN ROOM | p.13 c.2 | Yes_____ No_____ |
| 42. | BSC & CACI CABINETS EXHAUST THROUGH A HEPA FILTER & THEN VENT OUTSIDE | p. 8 c. 1 | Yes_____ No_____ |
| 43. | PERSONNEL COMPOUNDING HAZARDOUS DRUGS HAVE ADDITIONAL TRAINING ON SELF PROTECTION | p.8 c.1 | Yes_____ No_____ |
| 44. | DISPOSAL PROCEDURES ARE IN ACCORDANCE WITH FEDERAL & STATE REQUIRMENTS | 15-1-16.5 | Yes_____ No_____ |
| 46. | ADDITIONAL REQUIRMENTS FOR FACILITIES COMPOUNDING HIGH RISK DRUGS NA_____ | | |
| 47. | DOCUMENTATION OF ADDITIONAL TRAINING IN DEPYROGENATION OF EQUIPMENT & CSP CONTAINERS | p.10 c.2 | Yes_____ No_____ |
| 48. | DOCUMENTATION OF ADDITIONAL TRAINING IN STERILIZATION METHODS & VERIFICATION OF STERILITY | p.9 c.2 | Yes_____ No_____ |
| 49. | COMPOUNDING PERSONNEL MEDIA FILL TESTING SEMI-ANNUALLY | p. 28 | Yes_____ No_____ |
| 50. | DOCUMENTATION ON HEPA FILTER TESTING & AIR FLOW TESTING SEMI-ANNUALLY | p.30 | Yes_____ No_____ |
| 51. | INSPECTION DATES OF PRIMARY ENGINEERING CONTROLS | HORIZONTAL UNITS | NA_____ |
| 52. | | VERTICAL UNITS | NA_____ |
| 53. | | BARRIER ISOLATER UNITS | NA_____ |
| 54. | | BIOLOGICAL SAFETY CABINET | NA_____ |
| 55. | | | |
| 56. | USP–NF General Chapter <797> MAY BE DOWNLOADED AT THIS SITE: http://www.library.musc.edu/tree_docs/sccp/USP35-NF30_797.pdf | | |

57. INSPECTOR COMMENTS:

61. I recommend this licensure with the following stipulations:

63. I recommend this license be withheld because of the following:

SIGNATURE OF P. I. C. OR COMPOUNDING SUPERVISOR

DATE

INSPECTOR