West Virginia Board of Pharmacy

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STERILE PERMIT INSPECTION-USP STANDARDS

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

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

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32.	* BUFFER ROOM FOR COMPOUNDING MAINTAINS POSITIVE AIR PRESSURE	p.12 c.1	Y____N____	Y____N____
33.	* AIR SAMPLING & CERTIFICATION OF ROOM ISO STANDARDS IS DONE AT LEAST SEMI-ANNUALLY	p.14 c.2	Y____N____	Y____N____
34.	SURFACE SAMPLING OF WORK AREAS WITH GROWTH MEDIUM IS DONE & CULTURED & RESULTS LOGGED	p.14 c.1	Y____N____	Y____N____
35.	* ALL SURFACES OF CLEAN ROOM ARE SMOOTH, SEALED & FLOOR JUNCTURES ARE COVED	p.12 c.1	Y____N____	Y____N____
36.	* PLACEMENT OF PRIMARY ENGINEERING CONTROLLS CONFORM TO USP 797 GUIDELINES	p.13 c.1	Y____N____	Y____N____
37.	PLACEMENT OF PRIMARY ENGINEERING CONTROLS PERMIT CLEANING OF ALL SURFACES	p.13 c.1	Y____N____	Y____N____
38.	REQUIREMENTS OF AIR CHANGES PER HOUR (ACPH) IN ROOMS AND PEC	p. 12	Y____N____	Y____N____
39.	**ADDITIONAL REQUIREMENTS FOR FACILITIES COMPOUNDING HAZARDOUS DRUGS NA_____**			
40.	UP TO DATE REFERENCE MATERIAL ON HAZARDOUS DRUGS & THEIR HANDLING & STORAGE	p. 28	Y____N____	Y____N____
41.	BSC & CACI CABINETS MAINTAIN A NEGATIVE AIR PRESSURE TO CLEAN ROOM	p.13 c.2	Y____N____	Y____N____
42.	BSC & CACI CABINETS EXHAUST THROUGH A HEPA FILTER & THEN VENT OUTSIDE	p. 8 c. 1	Y____N____	Y____N____
43.	PERSONNEL COMPOUNDING HAZARDOUS DRUGS HAVE ADDITIONAL TRAINING ON SELF PROTECTION	p.8 c.1	Y____N____	Y____N____
44.	DISPOSAL PROCEDURES ARE IN ACCORDANCE WITH FEDERAL & STATE REQUIRMENTS	15-1-16.5	Y____N____	Y____N____
46.	SAFE HANDLEING AND STORAGE REQUIREMENTS ARE IN PLACE	USP 800	Y____N____	Y____N____
47.	**ADDITIONAL REQUIRMENTS FOR FACILITIES COMPOUNDING HIGH RISK DRUGS NA_____**			
48.	DOCUMENTATION OF ADDITIONAL TRAINING IN DEPYROGENATION OF EQUIPMENT & CSP CONTAINERS	p.10 c.2	Y____N____	Y____N____
49.	DOCUMENTATION OF ADDITIONAL TRAINING IN STERILIZATION METHODS & VERIFICATION OF STERILITY	p.9 c.2	Y____N____	Y____N____
	COMPOUNDING PERSONNEL MEDIA FILL TESTING SEMI-ANNUALLY	p. 28	Y____N____	Y____N____
50.	DOCUMENTATION ON HEPA FILTER TESTING & AIR FLOW TESTING SEMI-ANNUALLY	p.30	Y____N____	y____N____
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. *** If the facility meets "Low-Level CSP with 12 hour or less BUD" guidlines, it does not need to meet these requirements.**

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:

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SIGNATURE OF P. I. C. OR COMPOUNDING SUPERVISOR DATE INSPECTOR

ATTACH THIS FORM TO A COMPLETED OUT-PATIENT OR INSTITUTIONAL PHARMACY INSPECTION FORM.