

West Virginia Board of Pharmacy

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NEW STERILE PERMIT INSPECTION-USP STANDARDS

	E-Mail Address	Date
	Phone	Fax
	DEA License #	WVBOP #
	Pharmacist-in-Charge	License #
	Compounding Supervisor & License #	

THIS INSPECTION IS BASED ON WV PHARMACY LEGISLATIVE RULES & LAW
AND THE MOST CURRENT VERSION OF USP 797

Policy & Procedure
Record To be Kept

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

		Y	N	Y	N
29	* THE BUFFER (CLEAN) ROOM IS MAINTAINED AT ISO 7 ENVIRONMENT				
30	* BUFFER ROOM FOR COMPOUNDING MAINTAINS POSITIVE AIR PRESSURE				
31	* AIR SAMPLING & CERTIFICATION OF ROOM ISO STANDARDS IS DONE AT LEAST SEMI-ANNUALLY				
32	* ALL SURFACES OF CLEAN ROOM ARE SMOOTH, SEALED & FLOOR JUNCTURES ARE COVERED				
33	* PLACEMENT OF PRIMARY ENGINEERING CONTROLS CONFORM TO USP 797 GUIDELINES				
34	PLACEMENT OF PRIMARY ENGINEERING CONTROLS PERMIT CLEANING OF ALL SURFACES				
35	SURFACE SAMPLING OF WORK AREAS WITH GROWTH MEDIUM IS DONE & CULTURED & RESULTS LOGGED				
36	REQUIREMENTS OF AIR CHANGES PER HOUR (ACPH) IN ROOMS AND PEC				
37	THE PHARMACY MAINTAINS A WRITTEN QUALITY ASSURANCE PROGRAM WITH ANNUAL UPDATES				
* If the facility meets "Low-Level CSP with 12 hours or less BUD" guidelines, it does not need to meet these requirements.					
		Y	N	Y	N
38	A COPY OF USP CHAPTER <800> IS AVAILABLE IN THE PHARMACY				
39	ENTITIES THAT HANDLE HDS MUST INCORPORATE CHAPTER<800> STANDARDS INTO THEIR OCCUPATIONAL SAFETY PLAN.				
40	AN UP TO DATE COPY OF THE NIOSH LIST OF ANTINEOPLASTICS AND OTHER HDS USED IN HEALTHCARE IS MAINTAINED AND REVIEWED ANNUALLY.				
41	PERSONNEL MUST THOROUGHLY UNDERSTAND THEIR RESPONSIBILITIES OF FUNDAMENTAL PRACTICES AND PRECAUTIONS OF HANDLING HDS AND AN ONGOING EVALUATION SYSTEM IN PLACE.				
42	PROPER SIGNAGE FOR THE HAZARD IS DISPLAYED AT THE HD HANDLING AREAS (RECEIVING AN UNPACKING, STORAGE AND COMPOUNDING OF HDS) AND ONLY ACCESSIBLE TO AUTHORIZED PERSONNEL.				
43	HDS ARE STORED IN A SEPARATE AREA ON PROPER SHELVING (NOT ON THE FLOOR) IN A NEGATIVE PRESSURE ROOM WITH AT LEAST 12 ACPH (NON-STERILE) OR 30 ACPH (STERILE).				
44	STERILE AND NON-STERILE HDS MUST BE COMPOUNDED WITHIN A C-PEC LOCATED IN A C-SEC EXTERNALLY VENTED THRU A HEPA FILTER AND HAVE A NEGATIVE PRESSURE BETWEEN 0.01 AND 0.03 INCHES OF WATER COLUMN RELATIVE TO ALL ADJACENT AREAS WITH APPROPRIATE ACPH.				
45	IN ADDITION TO CHAPTER <800> STERILE COMPOUNDING MUST FOLLOW STANDARDS IN <797> THAT THE C-PEC PROVIDES ISO CLASS 5 AIR LOCATED IN A C-SEC OF ISO CLASS 7 AND AT LEAST 30 ACPH AND THE ANTEROOM BE OF ISO CLASS 7.				
46	SINK IS IN ANTE-ROOM AT LEAST 1 METER FROM ENTRANCE TO HD BUFFER ROOM.				
47	PROPER BUDS ASSIGNED BASED ON AREA IN WHICH COMPOUNDED AND RISK LEVEL.				
48	BSC & CACI CABINETS EXHAUST THROUGH A HEPA FILTER & THEN VENT OUTSIDE, SIX FEET ABOVE HIGHEST ROOF POINT.				
49	GLOVES FOR STERILE HD COMPOUNDING ARE STERILE CHEMOTHERAPY POWDER FREE GLOVES.				
50	GOWNS ARE DISPOSABLE AND NON-PERMEABLE THAT CLOSE IN THE BACK, LONG SLEEVES AND ELASTIC CUFF.				
51	TWO PAIR OF SHOE COVERS ARE DORNED BEFORE ENTERING THE C-SEC AND DOFFED WHEN EXITING THE C-SEC				
52	ALL PPE WORN DURING HD COMPOUNDING IS CONSIDERED CONTAMINATED AND DISPOSED OF PROPERLY ACCORDING TO LOCAL, STATE AND FEDERAL REGULATIONS				
53	IS ENVIRONMENTAL WIPE SAMPLING PERFORMED? (NOT REQUIRED AT PRESENT - BEST PRACTICE)				
54	DOCUMENTATION OF PERSONNEL OF REPRODUCTIVE CAPABILITIES UNDERSTANDING THE RISKS OF HANDLING HDS.				
55	SOPS TO ENSURE PROPER TRAINING OF PERSONNEL REGARDING PROPER RECEIVING, LABELING, TRANSPORT, STORAGE AND DISPOSAL OF HDS.				
56	TRAINING AND COMPETENCY ASSESSMENT IS DONE AT LEAST ANNUALLY AND DOCUMENTED (INCLUDING CUSTODIAL PERSONNEL).				
57	A SPILL KIT IS ACCESSIBLE IN THE RECEIVING AREA AND ALL OTHER AREAS HAVING HDS.				
58	SPECIFIC SOP IN PLACE TO PREVENT SPILLS AND TO MANAGE THE CLEAN UP OF HD SPILLS AND DOCUMENTATION				
59	SOPS ARE REVIEWED ANNUALLY AND DOCUMENTED AS SUCH.				
60	IS THERE AN INSTITUTED MEDICAL SURVEILLANCE PROGRAM? (NOT REQUIRED / BEST PRACTICE)				
61	POLICY AND PROCEDURES IN PLACE TO ENSURE WORKER SAFETY DURING ALL ASPECTS OF HANDLING HDS				

Inspector Comments:

Pharmacist-in-Charge	Date	Inspector	Date
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