

# West Virginia Board of Pharmacy

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**Charleston, West Virginia 25311**

## NON-STERILE COMPOUNDING INSPECTION REPORT

«Corporate_Name» «Pharmacy_Name» «Street_Address» «Mailing_Address» «City», «State» «Zip»	E-Mail Address «EmailAddress»	Date «Next_Insp»
	Phone «WorkPhone»	Fax «FaxNumber»
	DEA License # «DEA_License_»	WVBOP # «BOP_License_»
	P.I.C. «Pharmacist_in_Charge»	License # «License_»
	Hours «Pharmacy_Hours»	

INSPECTORS: When conducting this inspection, do so with a copy of the USP 795 Guidance in hand.

**Which of the following categories of compounds does this pharmacy prepare?**  
 SIMPLE \_\_\_ MODERATE \_\_\_ COMPLEX \_\_\_ NIOSH LISTED \_\_\_

Item	Question	Reference	Yes	No	NA
1	Does the pharmacy have a Compounding Policy & Procedures Manual?				
2	Does the pharmacy have copies of the USP Chapter 795 and the list of NIOSH HAZARDOUS DRUGS on hand?				
3	Does this facility prepare compounds for office use, not patient specific?	FDA Rules			
4	If so, is this pharmacy registered with the FDA as a 503(B) Outsourcing Facility?	FDA Rules			
5	Documentation of personnel training is readily available?	795 Page 2			
6	Documentation of the training includes compounding procedures??	795 Page 2			
7	Documentation of training includes proper use of equipment?	795 Page 2			
8	Documentation of training includes proper clean-up procedures?	795 Page 2			
9	Training includes proper storage, handling and disposal of Hazardous Drugs?	795 Page 2			
10	Does the Compounding Facility have adequate space for procedures?	795 Page 2			
11	Does the space allow for orderly placement of equipment?	795 Page 2			
12	Is the compounding area well lit?	795 Page 2			
13	Is only one preparation compounded at a time?	795 Page 2			
14	Procedures are in place to prevent cross-contamination?	795 Page 2			
15	Does the pharmacy perform hazardous compounding in a ventilated cabinet?	795 Page 2			
16	Is the Ventilated Cabinet certified and tested periodically?	795 Page 2			
17	Are the hood pre-filters checked and replaced regularly?	795 Page 2			
18	Is there a sink located in the compounding area?	795 Page 2			
19	Hot & cold water, soap/detergent, air-dryers or single use towels available?	795 Page 2			
20	Compounding personnel maintain good personal hygiene and clean clothing?	795 Page 2			
21	Appropriate protective attire available for Hazardous Drug compounding?	795 Page 2			
22	Is there adequate space for cleaning up used equipment?	795 Page 3			
23	Is purified water used as a final rinse?	795 Page 3			
24	Appropriate temperature and humidity monitors are maintained & documented?	795 Page 3			
25	Bulk ingredients are stored in a clean and sanitary condition?	795 Page 3			
26	Hazardous drugs are stored separately and handled by trained personnel?	795 Page 3			
27	Hazardous products are compounding in a separate area?	795 Page 3			

28	Separate equipment & utensils are used for hazardous compounding?	795 Page 3			
29	Trash is disposed of in a safe and sanitary method?	795 Page 3			
30	Compounding utensils are neither reactive or additive?	795 Page 3			
31	Equipment & utensils are available and cleaned regularly?	795 Page 3			
32	Scales, balances or other equipment used for measurement are valid?	795 Page 3			
33	Does the pharmacy compound medications that are similar to commercial products?	FDA			
34	If so, are they significantly different in the commercially available product?	FDA			
35	Are Certificates of Analysis obtained and reviewed for all bulk API's.	795 Page 4			
36	Are USP or NF grade components used, if available?	795 Page 4			
37	If not, are components chemically pure or American Chemistry Society certified?	795 Page 4			
38	Component expiration dates do not exceed 3 years?	795 Page 4			
39	Are all substances labeled with a lot number and expiration date?	795 Page 4			
40	Ingredients for oral consumption meet Food grade standards?	795 Page 4			
41	There are no preparations made that are listed on FDA withdrawn list?	FDA			
42	MSDS are readily accessible to all compounding personnel?	795 Page 6			
43	Master formulas are maintained for commonly prepared compounds?	795 Page 5			
44	Worksheets are prepared and maintained on all compounded products?	795 Page 6			
45	Worksheets record all personnel involved in the preparation?	795 Page 6			
46	Worksheet records list all components, lot #'s and expiration dates?	795 Page 6			
47	Worksheets contain documentation of assigned BUD?	795 Page 6			
48	Worksheets contain list of equipment to be used?	795 Page 6			
49	Worksheets list the mixing instructions?	795 Page 6			
50	Worksheets list container used for final product?	795 Page 6			
51	Worksheets list total product compounded?	795 Page 6			
52	Worksheets contain patient's name, Rx #, date of preparation?	795 Page 6			
53	Finished preparation is checked to insure it appears as expected?	795 Page 6			
54	Non-sterile water preparations BUD not later than 14 days refrigerated?	795 Page 5			
55	Non-aqueous formulations BUD no later than six months?	795 Page 5			
56	Or the actual expiration date of any API?	795 Page 5			
57	When a commercial product is used the BUD lesser of 25% of remaining or 6 months?	795 Page 5			
58	All other products, BUD no greater than duration of therapy or 30 days?	795 Page 5			
59	Quantities of batch preparations are appropriate based on historical records?	503(A)			
60	Blank Line				

Inspector Comments:

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«Pharmacist_in_Charge»	Date	«Inspector»	Date
Pharmacist-in-Charge		Inspector	