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Universal Inspection Form

WV Pharmacy License Number:			**Inspection Information**
Business e-Profile ID:		**Conference Call Date:**	
Legal Business Name:	#N/A	**Start Time: 24-hour format (13:00)**	
Doing Business As (DBA):	#N/A	**End Time: 24-hour format (13:00)**	
Address:	#N/A	**Onsite Inspection Date(s):**	
City:	#N/A	**Start Time(s): 24-hour format (13:00)**	
State:	#N/A	**End Time(s): 24-hour format (13:00)**	
Zip Code:	#N/A	**Inspector Name:**	#N/A
Telephone number:	#N/A	**Inspection Performed by (NABP, State, etc):**	
Fax number:	#N/A	**Observer Name/Affiliation (if applicable):**	
Website:		**Observer Name/Affiliation (if applicable):**	

Focused Information			
The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not			

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed (X)
	Start Time: (24-hour format)	End Time: (24-hour format)	
Sunday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	#N/A	#N/A	
Nonsterile Compounding Supervisor			
Sterile Compounding Supervisor			
Hazardous Compounding Supervisor			

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Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel			

Business Licensure Information for State (board of pharmacy, state controlled

License/Registration Agency	Business Name on License/Registration	License Number	Expiration Date
West Virginia Board of Pharmacy	#N/A	0	
Drug Enforcement Administration	#N/A	#N/A	
Inspector Notes: List states in which Non-Resident licenses are held			

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Attachments	
Document Name	**Description**

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	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Telepharmacy	
Open to the Public		Central Fill/Processing/Shared Services	
Closed Door		Specialty Pharmacy	
Drive-through window		Handles Medical Marijuana	
Mail/Deliver (in state)		Nuclear Pharmacy	
Mail/Deliver (out-of-state list below)		Manufacturer	
Veterinary Pharmacy		Wholesale Distributor	
Investigational Drugs, Clinical Trials/Research		Provide prescription drugs for "Office Use"	
Institutional		Outsourcing Facility	
Long-Term Care		Nonsterile Compounding	
HMO/PBM only		Nonsterile Hazardous Drug Compounding	
Internet Pharmacy (New Rx)		Sterile Compounding	
Internet Pharmacy (Refill Rx)		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements	
CNSPs for INDs		CSPs for INDs	
CNSPs which are essential copies of a commerically available drug product on the Drug Shortage List or justified by a documented medical need for an individual patient - If so, list		CSPs which are essential copies of a commercially available drug product on the Drug Shortage List or justified by a documented medical need for an individual patient - If so, list	
CNSPs sold OTC		CSPs sold OTC	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific:		Patient specific:	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
Distributed (eg non patient-specific):		Distributed (eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	
Types of CNSPs:		Categories of CSPs:	
Aqueous		Category 1 CSPs	
Nonaqueous		Category 2 CSPs	

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Specific types:		Category 3 CSPs	
Solid oral preparations		Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations:		Blood-derived or other biological material (eg autologous serum)	
Creams		Injections including infusions	
Gels		Irrigations for internal body cavities (eg bladder or peritoneal cavity)	
Ointments		Ophthalmic dosage forms	
Lotions		Aqueous preparations for pulmonary inhalation	
Nasal and sinus preparations:		Baths and soaks for live organs and tissues	
Nasal sprays		Implants/ Pellets	
Nasal irrigations		Other (please list):	
Other (please list):			

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Facility Size in Square Feet and Number of PECs		Personnel	
Total Pharmacy size:		Total Pharmacists:	
Nonsterile Compounding Room size:		Number of Compounding Pharmacists	
Nonsterile Compounding powder hoods number:		Total Graduate Students or Residents:	
Nonsterile Hazardous Drugs (HD) Compounding Room size:		Total Student Interns:	
Nonsterile HD Compounding CVE/BSC/CACI hoods number:		Total Technicians:	
Sterile Compounding Ante Room size:		Number of Compounding Technicians	
Sterile Compounding Clean/Buffer Room size:		Of technicians, how many are certified?	
Sterile Compounding Number LAFW hoods/areas:		Of technicians, how many are techs-in-training?	
Sterile Compounding Number BSC hoods:		Total Other Licensed Personnel:	
Sterile Compounding Number CAI/CACI hoods:		Total Other Unlicensed Personnel:	
Negative Pressure Sterile HD Room size:		Ratio #Tech:#RPh present at time of inspection:	
Sterile HD Compounding Number of BSC hoods:		Total Pharmacist Hours Per Week:	
Sterile HD Compounding Number of CACI hoods:		Total Technician Hours Per Week:	

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	

	Volume Dispensed		**Volume Distributed**
Total Prescriptions Dispensed/day:		Total Orders Distributed/day:	
% Veterinary Prescriptions		% Veterinary Orders	
% Controlled Substance Prescriptions		% Controlled Substance Orders	
% Nonsterile Compounded Prescriptions		% Nonsterile Compounded Orders	
% Sterile Compounded Prescriptions		% Sterile Compounded Orders	
% Hazardous Drugs (HD) Prescriptions		% Hazardous Drugs (HD) Orders	

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Definitions: DISPENSE means to provide a or compound to a prescriber or health care			
States to which the pharmacy Note: if not available, request information be			
State	**Volume Dispensed**	**Volume DISTRIBUTED**	**/day, week, month**
Alabama (AL)			
Alaska (AK)			
Arizona (AZ)			
Arkansas (AR)			
California (CA)			
Colorado (CO)			
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)			
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)			
Indiana (IN)			
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)			
Montana (MT)			

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Definitions: DISPENSE means to provide a or compound to a prescriber or health care			
States to which the pharmacy Note: if not available, request information be			
State	**Volume Dispensed**	**Volume DISTRIBUTED**	**/day, week, month**
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)			
New Mexico (NM)			
New York (NY)			
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)			
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)			
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)			
West Virginia (WV)			
Wisconsin (WI)			
Wyoming (WY)			
Other:			

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: #N/A
Business e-Profile ID:
WV Pharmacy License Number: 0
Inspection Date:

		Observation	Inspector Notes	USP Reference(s)
Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)				
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If "no", go to compliance statements.***			11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***			4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***			2, 11
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***			3.3, 11
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***			6.2, 11
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***			4.2, 11

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Nonsterile Compounding Inspection for USP <795>

Facility Name: #N/A
Business e-Profile ID:
WV Pharmacy License Number: 0
Inspection Date:

		Observation	Inspector Notes	USP Reference(s)
1.6	**Equipment**: The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***			6.1, 11
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***			6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***			7.1, 11
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***			9, 11
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***			11, 12 USP <1163>

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Nonsterile Compounding Inspection for USP <795>

Facility Name: #N/A
Business e-Profile ID:
WV Pharmacy License Number: 0
Inspection Date:

		Observation	Inspector Notes	USP Reference(s)
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***			1.1.3, 11, 12.1, 12.2, 12.3
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."***			11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspector should answer statement as***			11, 13.2
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***			12.1

Designated Person(s) and Personnel Training Program

Inspector must complete the <795> Records Review module to complete this section.

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: #N/A
Business e-Profile ID:
WV Pharmacy License Number: 0
Inspection Date:

		Observation	Inspector Notes	USP Reference(s)
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If "no", go to the compliance statements.***			1.1.4
2.1	The designated person(s) (for the QA program) has the training, ex perience, responsibility, and authority to perform the duties required of them.			1.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***			1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.			1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.			1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.			1.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.			1.1.4, 11
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.			1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If "no", go to compliance statements.***			2, 14

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: #N/A
Business e-Profile ID:
WV Pharmacy License Number: 0
Inspection Date:

		Observation	Inspector Notes	USP Reference(s)
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review for compounding personnel are answered "no" or "missing," this statement should be answered as "no". For details, see Records Review module.***			2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review for compounding personnel are answered "no" or "missing," this statement should be answered as "no". For details, see Records Review module.***			2, 14
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered non-compliant. For details, see the Records Review module.***			2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** ***Inspector should complete the <795> Records Review module question 3.0.***			2, 14
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If "no", go to compliance statements.***			3

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Nonsterile Compounding Inspection for USP <795>

Facility Name: #N/A
Business e-Profile ID:
WV Pharmacy License Number: 0
Inspection Date:

		Observation	Inspector Notes	USP Reference(s)
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***			
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.			3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***			3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.			3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If "no", go to compliance statements.***			3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.			3.2 Box 1
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***			3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.			3.3
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If "no", please list the garb worn for the type of component and compounding activity.***			3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.			3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).			3.3

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: #N/A
Business e-Profile ID:
WV Pharmacy License Number: 0
Inspection Date:

		Observation	Inspector Notes	USP Reference(s)
6.7	Gowns that are reused do not leave the compounding area.			3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).			3.3
6.9	Soiled garb is disposed of or sent for laundering.			3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.			3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?			3.3
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If "no", go to compliance statements.***			4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.			4.1
8.2	The compounding area is well lit.			4.1
8.3	The compounding area is clean and sanitary.			4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).			4.1
8.5	The compounding area is in a good state of repair.			4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.			4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.			4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.			4.1
9.0	Is the compounding area free of carpet?			4.1

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: #N/A
Business e-Profile ID:
WV Pharmacy License Number: 0
Inspection Date:

		Observation	Inspector Notes	USP Reference(s)
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If "no", go to compliance statements.***			4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***			4.2
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***			4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***			4.2
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***			4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.			4.2
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).			4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.			4.2

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		Observation	Inspector Notes	USP Reference(s)
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***			4.2
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If "no", go to compliance statements.***			4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.			4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.			4.3
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.			4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).			4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.			4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***			4.3 USP <1231>
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***			5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If "no", go to compliance statements.***			5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.			5 Table 1

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		Observation	Inspector Notes	USP Reference(s)
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.			5 Table 1
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components**.			5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.			5 Table 1
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***			5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.			5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.			5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***			5
	Equipment and Components			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***			6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If "no", go to compliance statements.***			6.1

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		Observation	Inspector Notes	USP Reference(s)
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***			6.1
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If "no", inspector should describe observations.***			6.1
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.***			6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***			6.1
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***			6.1

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18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as "no". If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***			6.1
19.0	Does the pharmacy compounding CNSPs use APIs?			6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If "no", go to compliance statements.***			6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***			6.2.1
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***			6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***			6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?			6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***			6.2.1
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If "no", go to compliance statements.***			6.2.2

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		Observation	Inspector Notes	USP Reference(s)
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***			6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).			6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations (797), 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***			6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.			6.2.2
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.			6.2.2
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If "no", go to compliance statements.***			6.2.3, 6.2.4
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).			6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.			6.2.3

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		Observation	Inspector Notes	USP Reference(s)
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.			6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.			1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.			6.2.4
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***			6.2.4
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If "no", go to compliance statements.***			6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).			6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.			6.2.5, 14

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		Observation	Inspector Notes	USP Reference(s)
26.3	The pharmacy has a readily accessible spill kit in the compounding area.			6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.			6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.			1.1.3, 6.2.5
	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If "no", go to the compliance statements.***			7.1
27.1	An MFR is created for each unique formulation.			7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.			7.1
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***			7.1, 10.2 Table 4

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		Observation	Inspector Notes	USP Reference(s)
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If "no", go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***			7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.			7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).			7.1
28.3	MFR includes the type of container–closure system(s).			7.1
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***			7.1
28.5	MFR has a physical description of the final CNSP.			7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.			7.1
28.7	MFR contains the reference source to support the assigned BUD.			7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.			7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.			7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.			7.1
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If "no", go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***			7.2, 14
29.1	A CR is completed for each CNSP prepared.			7.2, 14

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29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.			7.2, 14
29.3	The CR includes the date (or date and time) the CNSP was prepared.			7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).			7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.			7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.			7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.			7.2, 14
29.8	The CR includes the weight or measurement of each component.			7.2, 14
29.9	The CR identifies the total quantity compounded.			7.2, 14
29.10	The CR lists the assigned BUD and storage requirements.			7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.			7.2, 14
29.12	The CR has a physical description of the final CNSP.			7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).			7.2, 14
29.14	The CR contains a MFR reference for the CNSP.			7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.			7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.			7.2, 12.1, 14

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30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation.*** ***Inspector should describe their observations in the Inspector Notes.***			2, 7.2, 8
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If "no", go to compliance statements.***			9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***			9
31.2	The labeling meets any state or federal regulatory requirements.			1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).			9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).			9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.			9
31.6	The label on the immediate container includes the BUD. ***If "no", please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***			9
31.7	The label on the immediate container includes the dosage form.			9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.			9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***			9

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		Observation	Inspector Notes	USP Reference(s)
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: This is a USP recommendation.***			9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***			9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CSNP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A*** .			9
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date."*** ***If "no", go to compliance statements.***			10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.			10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.			10.1
36.3	BUDs are assigned from the date (and time) of preparation.			10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***			10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.			10.4

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: #N/A
Business e-Profile ID:
WV Pharmacy License Number: 0
Inspection Date:

		Observation	Inspector Notes	USP Reference(s)
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If "no", inspector should describe the observations, including the name of the***			10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If "no", who establishes the maximum BUD for a MFR?***			7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?			10.5
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If "no", go to compliance statements.***			10.5
40.1	Pharmacy staff have access to the USP monograph for reference.			10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If "no", inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed***			10.5
40.3	Components used by the compounder match those listed in the monograph. ***If "no", describe the source of the component in monograph and the source that the pharmacy used***			10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If "no", identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***			10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?			10.4

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		Observation	Inspector Notes	USP Reference(s)
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are not following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** ***If "no", go to compliance statements.*** ***If all CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***			10.4
42.1	**Non-preserved, Aqueous Dosage Forms**: The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If "no", describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***			10.4 Table 4 USP <659>
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If "no", describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***			10.4 Table 4 USP <659>

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Nonsterile Compounding Inspection for USP <795>

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		Observation	Inspector Notes	USP Reference(s)
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If "no", describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***			10.4 Table 4 USP <659>
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If "no", describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***			10.4 Table 4 USP <659>
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?			10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If "no", go to compliance statements.***			10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If "no", collect a copy of the MFR, the CR, and a copy of a label without PHI.***			10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If "no", collect a copy of the MFR, the CR, and a copy of a label without PHI.***			10.5

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		Observation	Inspector Notes	USP Reference(s)
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as non-compliant and describe observations.***			10.5
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If non-compliant, please describe the inspector observations.***			10.5
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If non-compliant, please describe the inspector observations.***			10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If "no", describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***			10.5

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		Observation	Inspector Notes	USP Reference(s)
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***			10.5
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If "no", go to compliance statements.***			1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***			12
45.2	The QA/QC programs address adherence to procedures.			12
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.			12
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***			12
45.5	The QA/QC programs address appropriate investigations and corrective actions.			12

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		Observation	Inspector Notes	USP Reference(s)
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?			12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If "no", go to compliance statements.***			12.2

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		Observation	Inspector Notes	USP Reference(s)
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***			12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.			12.2
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.			12.2
47.4	Complaints are fully investigated.			12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.			12.2
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***			12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.			1.1.3, 12.2

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		Observation	Inspector Notes	USP Reference(s)
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, inspector should answer the question as "No".***			12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If "no", go to compliance statements.***			12.1, 12.2, 12.3
49.1	The pharmacy has procedures to determine when recalls must be initiated.			12.1
49.2	The pharmacy documented the implementation of the recall.			12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).			1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.			12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***			12.1
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If "no", go to compliance statements.***			13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.			13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).			13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).			13.1

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		Observation	Inspector Notes	USP Reference(s)
Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*				
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If "no", go to compliance statements.***			
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).			3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.			3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).			3.1
53.4	Personnel removed earbuds or headphones.			3.1
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***			3.1
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If "no", go to compliance statements.***			3.2, Box 1
54.1	All personnel who enter the compounding area to compound performed hand hygiene.			3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.			3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.			3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.			3.2
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If "no", go to compliance statements.***			3.3 Box 1

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		Observation	Inspector Notes	USP Reference(s)
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).			3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***			3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.			3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***			3.3
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.			
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If "no", go to compliance statements.***			2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.			3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.			4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.			7, 7.1 Box 2
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***			3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.			3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***			6.2 (6.2.1 - 6.2.5)

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		Observation	Inspector Notes	USP Reference(s)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***			6.1 Table 2
58.8	The compounding personnel have knowledge of and access to any SDS.			6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).			1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If "no", inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***			7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***			7.2, 14 Box 3
58.12	Documentation in the CR is legible. ***If "no", collect copy of record that is illegible. Redact any PHI on record.***			14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.			10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If "no", describe observations in Inspector Notes.***			7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.			8.1 Box 2
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***			9
58.17	The compounding personnel completed any documentation on the CR. ***If "no", describe observations of what was missing or omitted in Inspector Notes.***			7.2, 8, 14 Box 3

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		Observation	Inspector Notes	USP Reference(s)
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.			5
59.0	**Final CNSP check observation**: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If "no", go to compliance statements.***			8, 8.1, 9
59.1	CSNP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).			8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).			8, 8.1
59.3	CNSP label was verified against the prescription or medication order.			8, 8.1, 9
59.4	CNSP label was verified against the MFR.			8, 8.1, 9
59.5	CNSP label was verified against the CR.			8, 8.1, 9
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.			8, 8.1
59.7	All checks and inspection that are performed are properly documented.			8.1, 14
59.8	CSNP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal.			8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***			12

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National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: #N/A
Business e-Profile ID:
WV Pharmacy License Number: 0
Inspection Date:

		Observation	Inspector Notes	USP Reference(s)
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If "no", go to compliance statements.***			5
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.			5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***			5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).			6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.			5 Table 1

NS <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (e.g., long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title						**Notes**
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						
1.1	Compounding personnel are trained on facility SOPs.						
1.2	Compounding personnel are trained on USP <795> standards.						
1.3	The training record for hand hygiene is complete.						
1.4	The training record for garbing is complete.						

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Inspection Date:

		Observation	Inspector Notes				USP Reference(s)
1.5	The training record for cleaning and sanitizing is complete.						
1.6	The training record for handling and transporting components and CNSPs is complete.						
1.7	The training record for measuring and mixing is complete.						
1.8	The training record for proper use of equipment is complete.						
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.						
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.						
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.						
1.12	The training record for spill management is complete.						
2.0	The annual competency assessment was evaluated and documented on the following topics:						
2.1	Compounding personnel are re-trained on facility SOPs.						
2.2	Compounding personnel are re-trained on USP <795> standards.						
2.3	The annual competency assessment for hand hygiene is complete.						
2.4	The annual competency assessment for garbing is complete.						
2.5	The annual competency assessment for cleaning and sanitizing is complete.						
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.						
2.7	The annual competency assessment for measuring and mixing is complete.						
2.8	The annual competency assessment for proper use of equipment is complete.						
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.						
2.10	The annual competency assessment for interpreting a COA is complete.						
2.11	The annual competency assessment for how to read/interpret a SDS is complete.						
2.12	The annual competency assessment for spill management is complete.						
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A. Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*						

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	Observation	Inspector Notes	USP Reference(s)

ALL QUESTIONS HAVE NOT BEEN ANSWERED, PLEASE REVIEW!

#N/A

#N/A